EXHIBIT 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO PLAINTIFFS: Joy Essman Case No. 2:12-cv-00277 Christine Wiltgen Case No. 2:12-cv-01216 Shirley Walker Case No. 2:12-cv-00873 Julie Wroble Case No. 2:12-cv-00883 Nancy Jo Williams Case No. 2:12-cv-00511	

The deposition of GREGORY BALES, M.D. taken before Pauline M. Vargo, an Illinois Certified Shorthand Reporter, C.S.R. No. 84-1573, at the law offices of Drinker, Biddle & Reath, 191 North Wacker Drive, Suite 3700, Chicago, Illinois, on April 1, 2016, at 8:02 a.m.

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I N D E X

Friday, April 1, 2016

E X H I B I T S

BALES EXHIBIT		MARKED FOR ID
Exhibit 1	Notice to take Deposition of Gregory T. Bales, M.D.	7
Exhibit 2	Defense Expert General Reports of Gregory Bales, M.D.	18
Exhibit 3	Ethicon Advisory Board Engagement Letter ETH.MESH.09280802 through ETH.MESH.09280808	18
Exhibit 4	E-Mail Chain, Top E-Mail sent 4/21/06 from Amy Vie ETH.MESH.07939396 and ETH.MESH.07939397	18
Exhibit 5	6/18/09 E-Mail ETH.MESH.00542924	20
Exhibit 6	2/26/10 E-Mail ETH.MESH.05740486	21

E X H I B I T S
Continued

BALES EXHIBIT		MARKED FOR ID
Exhibit 7	E-Mail Chain, Top E-Mail sent 8/15/05 ETH.MESH.02923305 and ETH.MESH.02923306	55
Exhibit 8	Chmielewski, et al., Study, "Reanalysis of a randomized trial of 3 techniques of anterior colporrhaphy using clinically relevant definitions of success"	61
Exhibit 9	Sand, et al., Study, "Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles"	64
Exhibit 10	Funk, et al., Study, "Long-term outcomes of vaginal mesh versus native tissue repair for anterior vaginal wall prolapse"	67
Exhibit 11	Oversand, et al., Study, "Long-term follow-up after native tissue repair for pelvic organ prolapse"	68
Exhibit 12	Iglesia, et al., Study, "Three-Year Outcomes of Vaginal Mesh for Prolapse"	69
Exhibit 13	Visco, et al., Study, "Vaginal mesh erosion after abdominal sacral colpopexy"	71
Exhibit 14	"GyneMesh II New Mesh Design" ETH.MESH.12009028 through ETH.MESH.12009035	77

E X H I B I T S
Continued

BALES EXHIBIT		MARKED FOR ID
Exhibit 15	Abed, et al., Study, "Incidence and management of graft erosion, wound granulation and dyspareunia following vaginal prolapse repair with graft materials: a systematic review"	81
Exhibit 16	Jacquetin, et al., Study, "Total transvaginal mesh technique for treatment of pelvic organ prolapse: a 3-year prospective follow-up study"	83
Exhibit 17	Jacquetin, et al., Study, "Total transvaginal mesh technique for treatment of pelvic organ prolapse: a 5-year prospective follow-up study"	85
Exhibit 18	Jacquetin/Cosson Study, "Complications of vaginal mesh: our experience"	86
Exhibit 19	Lowman, et al., Study, "Does the Prolift system cause dyspareunia?"	92
Exhibit 20	Weber, et al., Study, "Sexual function and vaginal anatomy in women before and after surgery for pelvic organ prolapse and urinary incontinence"	94
Exhibit 21	Cochrane Review, "Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse"	105
Exhibit 22	Maher article, "The Transvaginal Mesh Decade"	109

E X H I B I T S
Continued

BALES EXHIBIT		MARKED FOR ID
Exhibit 23	Maher paper, "Vaginal mesh contraction, definition, clinical Presentation and Management"	116
Exhibit 24	Dietz, et al., Study, "Mesh contraction: Myth or reality?"	122
Exhibit 25	Abstract 157 by Letouzey and De Tayrac	134
Exhibit 26	PowerPoint, "Mesh shrinkage: How to assess, how to prevent, how to manage?"	136
Exhibit 27	Gynecare Prolift IFU	199
Exhibit 28	2015 Gynemesh PS IFU	202
Exhibit 29	Urology Times Urology Excerpt	203
Exhibit 30	Ek, et al., Study, "Urodynamic Assessment of Anterior Vaginal Wall Surgery: A Randomized Comparison Between Colporraphy and Transvaginal Mesh"	214
Exhibit 31	Rogowski, et al., Article, "Mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair"	215

(The witness was duly sworn.)

GREGORY BALES, M.D.,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MS. THOMPSON:

Q. Good morning, Dr. Bales.

A. Good morning.

Q. My name is Margaret Thompson, and I represent the Plaintiffs in the Ethicon MDL. Is that your understanding? And we just met, right?

A. That's correct.

Q. And we are here this morning to take your deposition regarding your general opinions regarding the Ethicon prolapse devices. Is that your understanding as well?

A. That's my understanding.

MS. THOMPSON: And we will go ahead and mark the notice as Exhibit 1.

(Bales Exhibit 1 was marked for identification.)

BY MS. THOMPSON:

Q. Have you seen the deposition notice? And this may actually not be the most recent one,

but I think the only thing that's changed here is the times.

A. Yes, I think I have seen this.

Q. Did you bring anything with you in response to the list of items that you were expected to produce?

A. I have some items.

Q. What did you bring with you?

A. So, I have my general report. I guess maybe you have it or you want it marked as an exhibit.

Q. I have it also.

A. And I have some of the case-specific things which I'm doing later and such.

Q. Okay. But nothing else?

MR. MORIARTY: Not true. We have invoices.

MS. THOMPSON: Okay, good.

THE WITNESS: And we have invoices.

MR. MORIARTY: But these are all case specific. You can ask him about his invoice for the general report or I can tell you about it. The bottom line is he hasn't sent that bill yet.

MS. THOMPSON: Okay. I will just ask him about it then. That's fine.

MR. MORIARTY: But these are case-specific invoices.

THE WITNESS: I'm a little bit behind in some of the invoice notations.

BY MS. THOMPSON:

Q. I understand. Dr. Bales, do you have an estimate of the time that you have spent in the case to this point working on your general opinions in the general report?

A. Strictly just the general?

Q. Yes.

A. You know, I would have to tabulate it exactly, but it has got to be around ten hours, approximately.

Q. And how much are you charging per hour?

A. So my rates for record review and discussions and such, it's 600 an hour and then the depositions, it's 750 an hour.

Q. Have you had your deposition taken before in any matter?

A. In other cases in the past?

Q. Yes.

A. Yes, ma'am.

Q. How many times?

A. Probably 30 or 40 over the last 15 years.

Q. And what was the nature of those depositions, just in general terms?

A. Typically it was single case-specific litigation, you know, on the plaintiff or defense side, where there was most frequently a surgical misadventure of one sort and I was asked to give an opinion about the surgical case and the outcome and things like that.

Q. So those would be primarily medical malpractice cases?

A. Medical malpractice.

Q. And you have testified on both sides?

A. I have testified on both sides.

Q. And what do you mean -- because I noticed this in your report too. What do you mean by "surgical misadventure"?

A. It's just a very global term with if there was any, I guess, allegation of, you know, misuse of an instrument, cutting the wrong structure, any type of surgical complication. So,

that's just a very sort of nonspecific term related to any aspect of a surgical procedure where there was some question raised.

Q. So the question would be raised as to whether the doctor was at fault with a complication of one kind or another?

A. Yes. Typically these are all, yeah, single patient/one doctor type cases and situations.

Q. Are all the opinions that you intend to offer contained in the general report that you issued?

MR. MORIARTY: Objection to form. Go ahead.

Q. Regarding general opinions.

MR. MORIARTY: Objection. Go ahead.

A. Well, I will answer all the questions to the best of my ability. If you ask me things outside the context of things I have already written, I will certainly offer those opinions, but I think most of my opinions will be consistent with what has been written down and produced.

Q. Fair enough. Are your opinions objective?

MR. MORIARTY: Objection.

A. Yes, I believe my opinions are objective. They are opinions to my best ability to give an opinion based on my own training and to my best degree of medical certainty, if you will.

Q. And are your opinions unbiased?

MR. MORIARTY: Objection. Go ahead.

A. I think my opinions are unbiased.

Q. When you prepared -- did you prepare the report yourself?

A. I did.

Q. And how did you decide what to include and what not to include in your report?

MR. MORIARTY: Objection. Go ahead.

A. Well, as you can guess, you know, there is a voluminous amount of information that can go into a report like this and there is, you know, years and years of documents, scientific papers, research articles, journal articles and abstracts, et cetera. So, you sort of pick and choose and you try to get a broad array of Level 1 evidence that reflects good science. That's what I try to include.

Q. Did you receive materials from defense

counsel as you were preparing your general report?

A. Well, there was conversations and e-mails about certain papers and abstracts and journals and such and things I looked up on my own.

Q. Did you do any kind of literature search on your own?

A. Yes. I do literature searches all the time, and I certainly, you know, do literature searches consistently in my occupation, being an academic at the University of Chicago; and certainly I did some literature search and looked back at some of these manuscripts in the preparation of my report.

Q. Did you search for particular products, for example?

A. Well, in general just we started obviously with sort of pelvic organ prolapse, and I'm familiar with a lot of literature just because I have been reviewing it and I review the Journal of Urology and Urology and Neurourology and Urodynamics. But again, and I looked at some case-specific things regarding the Prolift and, you know, the Ethicon products.

Q. Did you receive any internal Ethicon

documents, corporate documents?

A. Yes, some.

Q. Did you ask for any internal corporate documents on any particular issue?

A. I didn't specifically ask for any.

Q. Why not?

A. I think as a doctor, obviously, most of the opinions I'm asked to give are based on my training and my review of the medical and scientific literature. So, things internal to a company in terms of e-mails and things like that, that's probably I guess for my purposes I feel a little less relevant, so I didn't specifically ask for those.

Q. Did you think that the internal corporate documents would not alter your opinions? Is that a reason?

MR. MORIARTY: Objection.

A. No, I didn't really give it any thought like that. As I said, typically when I -- and you asked earlier. I have been involved in other sort of medical malpractice cases and stuff, and so I usually again rely on, you know, articles and peer-reviewed literature, you know, that's in the

medical and surgical literature. I don't typically rely on, you know, corporate e-mails or documents like that. So, honestly, I don't think that typically -- I wouldn't think to typically ask and review all of that.

Q. So, if Ethicon had information that wasn't contained in the medical literature, would that be important to you?

A. Well, that's an awfully broad statement. I guess it would depend on what the nature of that information was. Can you be more specific?

Q. We may be later on as I maybe show you some things.

A. Okay.

Q. When did you first begin working as a paid consultant for Ethicon?

A. So, probably, if you include sort of some of the work I did with Ethicon 10 or 12 years ago, I used to train some doctors on doing TVT procedures. That probably started back in 2000, 2001, so that would be sort of the introduction.

Q. And have you worked as a paid consultant for Ethicon in every year since then?

A. So, no, definitely not. Early on when

TVT first came online, a lot of doctors wanted to use and learn that technique, and I was one of the earlier doctors and one of the first surgeons in the Chicagoland area doing TVT. So, for the first few years I did do a lot of training and consulting, but then for a number of years I didn't do any.

Q. When did you start working for Ethicon as a paid consultant on prolapse devices?

MR. MORIARTY: Objection. Are you talking about litigation?

MS. THOMPSON: No, I'm not talking about litigation.

BY MS. THOMPSON:

Q. Why don't you go ahead and tell me what your roles have been with Ethicon outside of litigation.

A. Sure, of course. So, essentially both, as we just mentioned, with TVT I did some proctoring and consulting. Essentially it would encompass two things. Doctors would come to the hospital and watch me do procedures and a couple of times I would go and help a doctor at their facility, and I did that early on in 2000, 2001

with TVT and then a few times, nowhere near as much, a handful of times with Prolift.

Q. So you have acted as a consultant, correct?

A. Correct.

Q. Have you taught courses as well?

A. I don't believe I have ever taught a course.

Q. And you proctored individual surgeons?

A. And proctored individual surgeons, yes.

Q. Have you taught any cadaver labs?

A. I don't think so. I have taught cadaver labs but I think for other companies. I don't believe I have ever done that with Gynecare. I don't remember exactly. This goes back ten years, but I don't think so for this company.

Q. And have you served on advisory boards?

A. Not to my knowledge, not for this, not for what we are discussing, for Gynecare products. I have been on advisory boards for some drug manufacturers and things like that.

MS. THOMPSON: Go ahead and mark the report as Exhibit 2, please, and let's go ahead and mark this Exhibit 3.

(Bales Exhibits 2 and 3 were marked for identification.)

BY MS. THOMPSON:

Q. Do you recognize this at all, Dr. Bales?

A. No, I don't, although, you know, it may be something that I saw, I don't know, ten years ago. But no, it doesn't look familiar to me as I look at it right now.

Q. And will you agree with me that that's a advisory board engagement letter and at least your name is listed as a member of the advisory board, but you don't remember being on a specific advisory board for Ethicon, right?

A. I don't.

MR. MORIARTY: Objection, form.

A. It might be as well that, you know, I went to a meeting or, you know, they had a program, if you will, and then they considered that an advisory board, if you will. But as I said, this must go back a lot of years, so, yeah, no, I'm sorry, I don't remember.

MS. THOMPSON: And Exhibit 4.

(Bales Exhibit 4 was marked for identification.)

BY MS. THOMPSON:

Q. This is an e-mail exchange about Prolift Users Forum from 2006. Did you participate in the Chicago Prolift Users Forum, to your memory?

A. Yeah, again, I apologize, my memory fails me on some of these things, but this was ten years ago. If it says I was at a forum one evening, then I guess I was, if my name is on this. But as I said, I really, I apologize, I can't remember ten years ago being part of this.

Q. When did you start using Prolift?

A. Probably about 2006, would be my best guess. I think it came online end of 2005.

Q. And if you did participate in this forum, that would be something that you would expect to be paid for by Ethicon, right?

MR. MORIARTY: Objection.

A. No, not necessarily. I mean, sometimes you participate in things because you wanted to get an opportunity to listen to other of your colleagues and other experts, and so I wouldn't necessarily expect to be paid, although oftentimes if you participate in things like this you would be paid.

MS. THOMPSON: Exhibit 5.

(Bales Exhibit 5 was marked for identification.)

BY MS. THOMPSON:

Q. This is an e-mail regarding payment for professional education in 2009 for Prolift in the amount of $18,000. Does that sound like that's something that was -- that you received and were paid for?

MR. MORIARTY: Objection, form and otherwise.

MS. THOMPSON: Let me rephrase that question. It was a bad question.

BY MS. THOMPSON:

Q. Do you recognize this?

A. I don't.

Q. Were you paid $18,000 in 2009 for professional education for Prolift?

A. I don't remember if I was. I hope I was. It's quite a bit of money, but I don't remember being paid $18,000 seven years ago.

Let me just add again that, you know, I have done proctoring and such for other companies too, and that's why sometimes it's a little hard to

remember my specific relationships with each individual vendor, so just to make that clarification, because I apologize if my memory perhaps doesn't serve me well.

MS. THOMPSON: That's okay, and Exhibit No. 6.

(Exhibit 6 was marked for identification.)

BY MS. THOMPSON:

Q. Showing you, Dr. Bales, a similar document from 2010. Do you recognize this document?

MR. MORIARTY: Objection.

A. No, I don't.

Q. And do you recall if you were paid $54,000 in 2010 for professional education?

A. No, I absolutely don't recall that at all. Does this reflect -- I mean, is this a check? Again, I'm not sure what this document is. I mean, is this a cancelled check? I mean, I don't recall being paid that amount of money at all. I hope I wasn't supposed to be paid that amount of money and it wasn't given to me. No. I apologize.

Q. As an Ethicon consultant proctoring

surgeons and now being retained as an Ethicon expert, you would agree with me that you probably know more about the Ethicon prolapse products than the average doctor in the community, wouldn't you?

A. Sure. If the average doctor in the community hasn't done these procedures, then I certainly would know more.

Q. Even doctors who have done the procedures, because of your academic position, your consulting positions with Ethicon, your knowledge of the literature, wouldn't you agree that you would know more than the typical community doctor?

MR. MORIARTY: Objection.

A. Sure. On balance I would agree that if it's something that a community doctor is less familiar with and less experienced with, I would know more.

Q. I would like to establish the Ethicon products that you actually intend to offer opinions on, so I would like to just go through and tell me whether you feel like your general opinions cover each of these products. Okay?

A. I'm at your disposal, counsel.

Q. Oh, that's nice to hear.

Gynemesh, a piece of mesh used transvaginally.

MR. MORIARTY: You mean Gynemesh PS?

MS. THOMPSON: Gynemesh PS.

A. Are you asking me if I'm going to offer opinions or you would like opinions?

Q. No. Do you intend to offer opinions on Gynemesh PS?

A. I think I'm here to answer your questions today, which I will do to the best of my ability; and I'm certainly happy to answer and offer opinions on Gynemesh PS, which I'm familiar with.

Q. The Prolift devices?

A. Correct.

Q. Prolift+M?

A. Correct.

Q. Prosima?

A. I've never used Prosima. I won't be able to tell you very much about Prosima. I'm familiar with it, but never personally had any experience using it myself.

Q. And I didn't notice any opinions regarding Prosima in your report, so can we assume

that you will not be offering opinions on the Prosima device?

A. I won't, especially if you don't ask anything more about it, so why don't you cross it out.

Q. Thanks. I will cross it out.

A. Perfect.

Q. So with the products that we just mentioned, is it your opinion generally that each of these products is safe and effective?

A. That would be my opinion.

Q. And is it your opinion generally that each of these products offer advantages over native tissue repairs?

A. Well, they may offer some advantages, and I think we would have to clarify more specifically what we are talking about. I think that's a little bit too broad for me to just say I agree.

Q. And it was meant as a broad question. Obviously there will be specific instances, but in general, do the products offer advantages in your opinion over native tissue repairs?

A. I think for certain things they offer

advantages.

Q. Is it your opinion generally speaking in the situations that the benefits would outweigh the risks?

A. Yes.

Q. What procedures are you currently performing for pelvic organ prolapse?

A. So the two primary ones are abdominal sacrocolpopexies, and those can be performed either through an open incision or robotically.

Also cystocele repairs, native tissue cystocele repairs or bladder prolapse repairs; posterior colporrhaphy or rectocele repairs; and colpocleisis. I think that encompasses all of them.

Q. And what is colpocleisis?

A. That's typically used for a patient who is much older and not sexually active and perhaps has associated comorbidities and may not be a good candidate for a lengthy surgical procedure where you more or less close off the vaginal opening. So, you prevent the prolapse, but then the vaginal is significantly foreshortened and essentially closed off, so a patient would no longer have the

ability to be sexually active.

Q. Is it your opinion that colpocleisis is a good choice for women who are not sexual active and have no plans to be sexually active in the future?

A. I think it's one of the choices and certainly should be used again in a woman who is not planning to be -- is either not or not planning to be sexually active.

Q. What are the risks of colpocleisis beyond the immediate operative risks?

A. Beyond the immediate operative risks? Well, it's a continuum. Obviously I think patients can develop infection and bleeding. Typically that would be more of a risk perioperatively, and you said you want to go kind of past that.

The big one is you can still re-develop prolapse, less commonly, but prolapse can still return. Patients may change their mind and get a new boyfriend, so there is always a small concern that the sexual issues may manifest themselves.

And the big one, of course, is pain. Any degree of pain and scarring from any surgical procedure in the vagina could manifest itself and

create and lead to continued pain and discomfort in the vaginal canal.

Q. Have you ever seen chronic pain related to colpocleisis in your practice?

A. Sure. Over 21 years I have seen patients who have had that procedure and have pain.

Q. How many cases of chronic pain after colpocleisis have you seen in your practice?

A. I wouldn't be able to quantify for that. It's a small number.

Q. Has it ever been reported in the medical literature, chronic pain after colpocleisis, that you are aware of?

A. I would think that it's been reported that after any vaginal procedure there is pain. I can't cite a specific paper where it has specifically said colpocleisis and chronic pain, but I would imagine it's out there.

Q. But today off the top of your head, you can't cite to any article that would address chronic pain related to colpocleisis procedures?

A. I can't cite a specific paper for you right now.

Q. Can you cite a paper with chronic pain

from cystocele repairs?

A. I'm going to have a hard time citing a specific paper about any questions you ask, because again, I just -- you know, I don't keep specific citations in my head, you know, on a consistent basis. So, probably any question you ask me to give you a specific citation, I'm not going to be able to do that. We will have to -- you know, I would have to get back with you and show you the, you know, the specific citation.

Q. How do you keep track of the complications with your patients with procedures that you have performed?

A. Well, I work -- so, I work at the University of Chicago, and we have a training program. We have three residents a year. Our residents frequently mine our data, and so we have ongoing databases and stuff.

So -- and we have a monthly morbidity and mortality meeting every single month which is a couple hours and is very labor-intensive because we go back through all the cases that have occurred. And again, that's part of our residents' job, is to mine the data and look for complications.

So, we are pretty aware of things. I mean, some things potentially get missed, but typically that's probably the best way. And of course, the obvious way are patients coming back to see me every six months or a year, and we keep track in that fashion, of course.

Q. But if a resident isn't mining a complication or it hasn't been presented at an M and M conference, there is no ready access to your complication or your complications rate, is there?

MR. MORIARTY: Objection. Go ahead.

A. Well, I guess the answer -- again, I'm not quite sure I fully understand, but if the patient had surgery and then never came back or never made me aware of a problem, a complication certainly could have occurred that I'm not aware of.

Q. Well, for example, when I asked the question about chronic pain after colpocleisis, you said it was very few but you couldn't tell me how many. Would you be able to go back and determine how many patients that you performed a colpocleisis have chronic pain?

A. Well, no. I have been practicing for 21

years, so I couldn't go back and quantify the number of cases I've done. I've done, you know, well into the thousands in terms of pelvic floor procedures between prolapse and slings and sacrocolpopexies.

So, I couldn't give you the denominator and I couldn't give you the numerator unless I went back and contacted the individual every patient. So, again, you asked me for a specific number, and I wasn't able to provide that.

Q. What Ethicon prolapse products are you currently using?

A. So, I currently primarily used the TVT, which is a sling product, and the TVT obturator, which again is a sling product but the sling is placed in a slightly different fashion. It's not retropubic but it goes through the obturator foramen.

Q. So you are currently not using any Ethicon products to treat prolapse?

A. I'm not as far as I know. I think many of them are off the market. I'm not sure they are available, but no, I'm not.

Q. Do you use Gynemesh PS in your abdominal

sacrocolpopexies?

A. I used Gynemesh PS for my sacrocolpopexies for a long time. Sometimes I'm at the whim of the University of Chicago. They sometimes they get other products in, so sometimes it's not up to me.

Currently the product they have for that application is the AMS product called IntePro, but again, unfortunately, sometimes the doctors don't have any ability to -- to -- weren't involved in the decision-making.

Q. How many Prolift procedures have you performed over your career, approximately?

A. So, just to clarify, there is total Prolift, there is anterior Prolift and posterior Prolift, so there is sort of three. You want an estimate based on all those procedures put together?

Q. Why don't you give me all and then break them down as to how many of each.

A. So, I would -- roughly, again it's a rough guesstimate. This goes back again ten years or so. Probably several hundred of -- probably several hundred of all of them, and then the

breakdown would be probably 50 percent anterior Prolift, probably 45 percent total Prolift and a very smaller -- a much smaller percentage, 5 percent or less of the posterior Prolift.

Q. Have you published any peer-reviewed articles regarding using vaginal mesh for prolapse repairs?

A. Yes.

Q. What are those articles?

MR. MORIARTY: Objection.

A. Again, I mean, I think my CV -- do we have my CV here? I would have to show you. I don't remember the exact citation.

Q. Did you bring your CV?

A. I don't think I have a copy of my CV.

MR. MORIARTY: We produced it with the report and reliance list.

BY MS. THOMPSON:

Q. Okay. And do you treat mesh complications in your practice?

A. Absolutely. More complications than I care to.

Q. What are the most common mesh complications that you treat in your practice?

A. So, there is a variety. There is complications of exposures or extrusions where the mesh is sort of exposed and through the vaginal wall, and there is some pain complications that patients see which may or may not always be related to the mesh in any fashion necessarily. But patients come in with again after pelvic organ prolapse surgeries complaining of pain, and obviously the most common, I guess, is a recurrence of the prolapse, where they are coming in, they have already had a procedure and now it's failed and they need additional surgery.

Q. What type of pain complications do you treat related to mesh?

A. Well, as I said, I don't know if you can sometimes discern what's related to mesh and what isn't, but patients come in and they have pain in their pelvic floor, in their vaginal canal area, and we treat it. We treat it in combination with our physical therapists, and also we have some wonderful pain specialists. So, we treat all gamuts of pain with or without or whether or whether they have not had any kind of mesh procedure.

Q. And you are aware of literature with large case series, in the hundreds of patients, with mesh complications of which pain is frequently one, if not the most, common complication, correct?

MR. MORIARTY: Objection, form. Go ahead.

A. Yeah. Can we read that back? I'm sorry.

Q. You are aware of a large body of literature describing hundreds of patients with mesh complications, of which pain is one of the most common presentations, if not the most common presentation, correct?

MR. MORIARTY: Objection. Go ahead.

A. There is certainly a lot of literature that patients who have had mesh procedures come back and have pain. So, yes, on balance I would agree with that.

Q. And are you aware of any articles describing series of patients coming, presenting with pain for other prolapse procedures, native tissue repairs?

A. So, again, patients in a series, looking at patients who have pain after they have had some

type of surgical procedure, not involving mesh?

Q. Right. Are there any articles in the literature that you are aware of that describe large series of patients presenting with pain after native tissue pelvic prolapse repair procedures?

A. I think, yes. I think there is obviously significant bodies of literature looking at -- you know, longitudinal studies looking at patients after cystocele repairs, after rectocele repairs, and there is always a small percentage that have pain, so there is definitely --

Q. That was not my question.

Are you aware of any article in the medical literature that reports case series of chronic pain or any pain related to native tissue pelvic organ prolapse procedures?

MR. MORIARTY: Objection, asked and answered.

MS. THOMPSON: He answered -- no. Go ahead and answer it because you did not answer that question.

A. Again, maybe I'm not understanding it properly, but yes, there is literature that certainly underscores that pain occurs after mesh

and non-mesh type pelvic procedures.

Q. My question is, is there an article that describes a series of patients who present with pain after native tissue pelvic organ procedures?

I'm not talking about a study where the outcome is success rates or were longitudinal. I'm talking about case series of pain complications after native tissue pelvic organ prolapse repairs.

MR. MORIARTY: Only pain?

MS. THOMPSON: Well, any complications of which pain is -- if pain is mentioned as a significant factor.

MR. MORIARTY: Objection, asked and answered. Go ahead.

A. Yeah, I think there is -- yes, there is lots of literature looking at non-mesh based, and one of the outcomes they look at and talk about is pain.

Q. Okay. I do want you to show me that article that describes series of patients with chronic pain after native tissue prolapse repair, and I will let you look for that at the break and tell me what that is.

MR. MORIARTY: Objection. He has no

resource with which to do such research.

MS. THOMPSON: He can look at his reliance list.

MR. MORIARTY: He can pick it out of a reliance list, if he can.

MS. THOMPSON: He can Google chronic pain after native tissue pelvic --

MR. MORIARTY: He is not doing research as we sit here today, on or off the record.

BY MS. THOMPSON:

Q. As you sit here today, you are not aware of an article that describes a case series of chronic pain after native tissue repairs, are you?

MR. MORIARTY: Objection.

A. Again, you are going to have to -- you don't have to raise your voice, but you just have to ask the question differently so I understand it. If you are asking me --

Q. All right. My first question was, you are aware of many articles reporting complications of mesh, of which pain is one of the main ones, describing hundreds of patients who are presenting to mainly tertiary care centers with mesh-related

complications including pain?

A. Yes, but -- well, hold it.

Q. So let me ask this question. I'm asking you, are you aware of similar articles that you know -- you know they are there with mesh -- and I'm sorry to raise my voice, but it's frustrating not to get an answer to my question. You know the articles are there with mesh. I'm asking you, are you aware of a similar article with native tissue repairs?

MR. MORIARTY: Objection.

A. Yes. There is absolutely articles looking at outcomes of non-mesh pelvic surgical procedures that look at outcomes.

And in answer to the first part of your question, I'm not aware that there is a specific article that only cites pain. So what you are discussing, of course, is outcomes, and there is outcomes -- and that's the first part of your question -- that there is outcomes of mesh surgeries and patients complaining of pain, hundreds of patients. That's one of the complications. And that same literature exists with non-mesh repairs, and I would be happy -- not

today, but I'm sure I could find a reference at some point for you.

Q. Okay. I want you to look for that, please, and I would like to be provided with it because I'm certainly not aware of it.

Have you removed mesh in your practice?

A. Yes.

Q. What were the indications for the removal of mesh?

A. Typically a -- typically an exposure so that it was -- and the patient was often sexually active and patients who were obviously having some discomfort, both on the part of the patient and obviously the partner.

Q. Have you removed mesh for other complications?

A. I have removed mesh sometimes when there has been mesh inside the urinary tract, inside the urethra, inside the bladder. So, any mesh in a spot where it doesn't belong, I have removed it.

Q. Have you removed mesh for pain?

A. Well, in the cases I just mentioned mesh is being removed in part because of pain.

Q. So you have only seen pain when it's

been accompanied by exposure or erosion; is that your testimony?

A. Say that -- is there a question there?

Q. You said removed for pain when it is associated with other things and you mentioned exposure, erosion.

A. Right.

Q. Have you ever removed mesh for pain when there was not exposure or erosion?

A. Yes.

Q. And what were those situations?

A. Well, sometimes if there is a recurrence of prolapse or sometimes if there is a patient can just feel discomfort in a location where we think there is some mesh and we feel that is on our differential list for a source of the pain. So, in some of those situations I remove mesh, and sometimes the mesh has to be removed to do another repair.

Q. Is it your testimony that mesh itself doesn't cause pain unless it's associated with something else?

A. I think -- I think there is a whole lot of factors that cause pain, so you are going to

have -- I'm not quite sure how to answer your question. So, mesh -- maybe rephrase that again.

Q. Do mesh devices cause pain?

A. Any surgical procedure causes pain, including mesh devices.

Q. That wasn't my question. Okay.

And you will agree with me with any complication there are factors that are important as well as it occurs or it doesn't occur. For example, the rate at which it occurs is important, right?

A. The rate of how often the complication or how quickly it occurs?

Q. How often. How often a complication occurs is important, right?

A. Sure.

Q. And how severe the complication is is important, right?

A. Well, I'm the treating doctor, so yeah, any complication is important, and certainly the degree of and severity of the complication is important as well. Everything is important.

Q. And the responsiveness to treatment is important, right?

A. Sure.

Q. Whether you can treat the patient or not, whether they can get better with your treatment is important?

A. I would say that's important, sure.

Q. And whether or not the complication is permanent or temporary is important, isn't it?

A. Well, sure.

Q. And is it your testimony here today that considering all those factors that are important to you, pain complications with mesh are no different from pain complications with native tissue repairs; is that your testimony?

MR. MORIARTY: Objection, form. Go ahead.

A. I think again that's an awfully broad kind of question. I think -- I think there is pain syndromes, and pain issues before surgery are very difficult to treat and there is a lot of factors that can be involved; and so I think you see that sometimes after patients have had mesh surgeries, non-mesh surgeries, associated hysterectomies, everything. So, I think it really has to be a little bit more case specific to sort out what's

causing the pain on any individual patient.

Q. I want you to answer my question.

Is it your testimony considering the factors, the rate, the severity, the responsiveness to treatment, the permanence, that there is no difference between mesh repairs and native tissue repairs regarding pain?

MR. MORIARTY: Same objection. Go ahead.

A. Again, there is -- I mean, it depends on what we are talking about in terms of the pain. It's just such a broad statement. I think in general, yeah, I think it's probably the same, but I also don't think it is a good question because it's so broad.

Q. Do you hold yourself out as an expert in medical device design, Dr. Bales?

A. You know, it's funny. Whenever I've taken depositions -- you asked me earlier -- people ask are you an expert. And so, again, I'm a board-certified urologist, so the default answer is always, well, I'm an expert as a urologist, right? So, if you ask me if I'm an expert in other things and you sort of think, well, I'm not

board-certified in other areas, I'm a board-certified urologist, but I'm an expert in things that I do very commonly and things that I'm very experienced in.

So, again, medical devices, if the medical device is that I've used and very familiar with and I've held in my hand and I've placed into patients and I have done their surgeries, then yes, I guess I'm considered an expert.

Q. Have you ever designed a medical device?

A. I have not.

Q. Are you a biomaterials expert?

A. Again, sort of the same answer to the previous question. It depends on what biomaterials I guess we are talking about. But if we are talking about biomaterials that I'm familiar with, including some of the meshes and things that I've implanted in patients and held in my hand and have done hundreds of times, then I guess I'm certainly very familiar and a lot more knowledgeable than 99 percent of people.

Q. Have you ever looked at an explanted mesh device histologically?

A. So, yes, I suspect I have, and I've

certainly seen pictures of the histologic presentations, and yes, I'm sure I have been in our pathology department at least a couple times and looked at some of these things. But, you know, it will be very difficult for me to describe the histologic appearance.

Q. So you would not consider yourself an expert in pathology?

A. I'm very knowledgeable about pathology, but I'm certainly not an expert and be able to describe the specific pathologic features that a pathologist, a board-certified pathologist would be able to do.

Q. Are you an expert in regulatory affairs?

A. That's such a broad thing, what regulatory affairs are, that again I guess I can't say I'm any kind of expert in regulatory affairs. I'm not sure even what that means.

Q. How about industry standards for warnings?

MR. MORIARTY: Objection, form.

A. So, an expert in industry, you are asking me if I'm an expert in industry standards of warnings.

So, again, I'm not -- I'm not aware of what those standards may be, so I guess I'm not an expert in it.

Q. We are going to go through your report. I'm going to ask you some questions about some of your opinions contained in the report. If you want to follow along, you are welcome to.

On Page 3 --

A. Can I just -- let me make sure I'm just working off the same copy. You said you gave it that. Was that Exhibit 2? Was it Exhibit 2?

Q. Exhibit 2, correct.

A. Can I have it just to make sure? Go ahead. Thank you.

Q. At the bottom of Page 3 you start out talking about sacrocolpopexy and then you also talk about uterosacral ligament suspensions and sacrospinous ligament fixations. Do you perform either of those procedures?

A. Yes.

Q. When was the last time you performed either one and which one?

A. A long time ago, a number of years ago, five years ago.

Q. So for apical prolapse typically you would use a sacrocolpopexy?

A. That's correct.

Q. What's the exposure rate for sacrocolpopexy?

A. Again, there is studies that the numbers vary slightly, but I guess probably the best citation, since we were talking about citations, there was a multicenter trial out of JAMA, and again, I can't tell you the specific date and journal number, that I think the exposure rate was about 10 or 11 percent in this one particular study, and I think that included seven-year followup. I think it was 10, 10.5 percent, I believe.

It was mostly urogynecologists in that paper. It was published about two years ago. That's probably the best paper, I guess. As I said, I apologize I can't give you the exact citation. It was JAMA; I can tell you that.

Q. So it's your opinion that the exposure rate with sacrocolpopexy was 10 to 11 percent?

A. Well, again, I just answered your question that the literature suggests that it's 10

to 11 percent. I don't quote my patients that high a complication rate, but that's the number in the literature. There is other studies that we could tease out that say it's a little lower or a little higher.

Q. In the paragraph that you said these transvaginal approaches were not without unique risks, you say your sacral ligament suspensions were known to cause ureteral occlusion and 4 percent requiring reimplantation in one study. Those were all noted intraoperatively, correct?

A. I believe so because typically, as you know, you check that. After that procedure you want to make sure usually you give some dye to the patients to make sure you see a ureteric stream into the bladder. I can't tell you if 100 percent of those were noted intraoperatively or shortly in the postoperative period.

Q. And you would agree that none of those had any permanent sequelae as a result of having the ureteral injury, correct?

A. Oh, no, I wouldn't agree with that at all.

Q. What evidence do you have that any of

those 11 percent of patients had any kind of permanent problems associated with the ureteral occlusion that was corrected at the time of surgery?

A. Well, so I have probably done over 200 ureteral re-implants in my career, and I can tell you that patients who have ureteral reimplantations often have postoperative problems, including a reflux, they sometimes have a higher risk of pyelonephritis, they sometimes report pain.

Q. Are you aware of any of the patients in this series that had any kind of permanent sequelae as a result of those ureteral implantations?

A. I am not, but we would have to pull out that paper and see. But again, I'm basing my answer on my own personal experience of several hundred of these ureteral reimplantations.

Q. You say that the uterosacral ligament suspensions and sacrospinous ligament fixation had a -- you say unfortunately, both had a success rate of only 60 percent at two years.

What is the treatment, the retreatment rate from that, those studies, for the same conditions, the same procedures?

A. Cited in those particular papers? Is that what you are asking me?

Q. I don't want to look up those papers, but what is generally your knowledge of how many would require retreatment?

A. Oh, I think it's very variable, but I think it depends on obviously the severity of the symptoms. Not everybody.

Q. Would five percent sound about right?

A. I wouldn't be able to -- five percent overall, that only five percent get retreated?

Q. Yes.

A. That probably is low, but I'm sure you could find -- we would have to pull out the paper, and there are some papers that would suggest it is a low rate and some patients, it's a higher rate. Again, it depends on the severity of the symptoms.

Q. In the Barber study that you quoted in your paper, in your opinion, the retreatment was five percent. Would that surprise you?

A. I think you are reading it, holding the paper, so it wouldn't surprise me. I think it sounds like you are reading it right from the text, so that was what they found.

Q. Are you aware of any comparative trial with -- well, first of all, what Ethicon products are indicated for apical repair, transvaginal apical repair?

A. Now or in the past?

Q. In the past. There are none now, right?

A. As far as I know, there is none. For apical repairs it was the total Prolift.

Q. And are you aware of any study with total -- the total Prolift that shows better success rates than uterosacral ligament suspension or sacrospinous ligament fixation, any studies?

A. Off the top of my head, I'm not sure better. I think equivalent, but we would have to again pull out some of the papers.

Q. So is there any better results from Prolift total compared to the native tissue that you described?

MR. MORIARTY: For apical repair?

MS. THOMPSON: For apical repair.

MR. MORIARTY: Go ahead.

A. Again, I'm not aware that there is truly any real good head-to-head randomized, long-term followup. But to answer your question, no, I'm not

aware of as I sit here right now.

Q. So I'm curious why you would say unfortunately these procedures have a success rate of only 60 percent at two years when Prolift is no better. Is that an objective and unbiased statement in your report?

MR. MORIARTY: Objection, form. Go ahead.

A. So, again, the statement reads that unfortunately, these two procedures had a success rate of 60 percent in two years. So, that's -- again, that's a direct citation from that paper, so I don't know how more unbiased you can be, right? I'm citing this paper and putting in the success rate. So, I'm only just rehashing what again is in the medical literature.

Q. Does that paper say "unfortunately the success rate of 60 percent"?

A. So you are concerned about the "unfortunately"?

Q. Well, I just didn't notice an opinion in your report that said "Unfortunately, Prolift only has a 60 percent success rate."

A. Prolift isn't perfect either, and again,

that's not the sentence. But I guess if I had said "The Prolift repairs have a success rate of X," I guess I could have put "unfortunately" in front of that. It's unfortunate that any surgical procedure is less than 100 percent, so I guess --

Q. But you didn't put that in your report, though, did you?

A. It looks like I didn't.

Q. In the paragraph -- and unfortunately, we don't have time to go through all the literature, but I do want to highlight some of it.

So, in your paragraph, your short paragraph about colporrhaphy --

A. Can you tell me where that is?

Q. It is on Page 4.

A. Okay.

Q. You state that high rates of recurrence of 30 percent or more have been reported with colporrhaphy, particularly in the anterior compartment. What's the recurrence in the posterior compartment in the literature?

A. I think that again, like most of these things that we are going to be discussing, there is going to be various series where the numbers are

going to vary slightly, but it's probably 20 to 30 percent, especially if you follow these patients long enough.

That's actually, unfortunately, as you know, just not to lecture, but that's actually, unfortunately, one of the problems with our medical literature, is that a lot of these series, the followup is relatively short, so there is not enough papers looking at patients over a long enough period of time where the recurrence rates obviously go up, unfortunately.

Q. So it's your testimony that the failure rate of posterior -- native tissue posterior repairs is 20 to 30 percent?

A. Yes.

Q. Are you aware of any literature where posterior Prolift improves the failure rates in a posterior repair over native tissue?

A. I think -- I think some of the literature that's out there shows it to be equivalent. Again, I don't think there is a lot of great literature on long-term outcomes with the Prolift, but I don't know if it's better, to answer your question.

Q. So I want to look at some of the -- before we look at some of the efficacy literature, let's mark this as the next exhibit.

(Bales Exhibit 7 was marked for identification.)

BY MS. THOMPSON:

Q. You are certainly aware that some doctors feel that mesh complications are more serious than native tissue repair complications, correct?

MR. MORIARTY: Objection, form.

A. I suspect there is some doctors who feel that way, sure, definitely.

Q. Do you know Linda Cardozo?

A. No.

Q. Do you know her name?

A. I know the name.

Q. I'm going to show you an e-mail from 2005. When was the Prolift marketed, introduced into the market?

A. I think the end of 2005. I don't remember exactly. You might know better than me. I want to say it was sometime in 2005, towards the end of 2005.

Actually, here in my report -- let me familiarize myself. I'm sorry I don't remember everything exactly. It says it was introduced March 2005, so I think that's correct.

Q. So, this e-mail is from August of 2005.

A. August 2005, okay.

Q. Do you have that e-mail in front of you?

A. Which exhibit number is it?

MR. MORIARTY: 7.

BY MS. THOMPSON:

Q. This e-mail from Linda Cardozo states -- and sent to various individuals, including Ethicon employees. Is that your understanding from looking at this e-mail?

MR. MORIARTY: Objection.

A. Yeah. I mean, again, you just handed it to me, so again, I'm not -- I'm trying to figure out --

Q. Dr. Cardozo states that, "It's not that there were a lot of complications, it's severity and type of complications and these were just the perioperative ones. I still have major concerns regarding the erosion rate and possible problems with dyspareunia, and none of these have been

addressed in the data which we have been given to date."

Would you disagree with Dr. Cardozo that as of August 2005 that these problems had not been addressed?

A. I don't -- I apologize.

MR. MORIARTY: Objection. Go ahead.

A. I don't know Linda Cardozo. I don't want to opine on what this e-mail is exactly, but it sounds like she has some concerns, and she is entitled to have some concerns, but I don't know what she is citing, I don't know what complications she looked at. Again, it's hard for me to interpret what this is without more information.

Q. Dr. Bales, I didn't ask you to interpret what Dr. Cardozo was saying or what she was using. I'm asking you, would you disagree with the statement that the problems here discussed had not been addressed in the data provided to date in August of 2005?

MR. MORIARTY: Objection. Go ahead.

A. Yeah. In August 2005 I'm not aware of what we were discussing at that time, and that's the only reason. In order to agree or disagree, as

I said, I have to interpret this a little bit, and again, I just -- I don't remember what -- you know, what specific complications and such.

So, again, it's just hard for me to agree or disagree. Again, I'm not trying to be evasive, but it's just an e-mail, it's just so vague. I don't know what she is specifically referring to. She certainly has some concerns.

Q. I know she has concerns. I'm asking you. In August of 2005, shortly before you started using the Prolift, did you have any concerns?

A. Counsel, I have concerns about any surgical procedure I do.

Q. Well, you didn't have enough concern that prevented you from using the product, right?

MR. MORIARTY: Objection, form. Go ahead.

MS. THOMPSON: Well, if he would answer my questions it would be easier.

MR. MORIARTY: He is answering your questions. You may not like the answers.

MS. THOMPSON: Oh, I like the answers just fine.

MR. MORIARTY: Okay. So let's just --

BY MS. THOMPSON:

Q. Dr. Bales, you began using the Prolift in early 2006, I believe you said, correct?

A. I think that's correct.

Q. If you had had concerns like Dr. Cardozo, you wouldn't have used it, right?

MR. MORIARTY: Objection.

A. No. That's completely incorrect. And actually, if you look just a little further, she is even -- I mean, well, it's kind of funny. As I said, I don't want to try to interpret this too much because I've just said I can't, but if you read another sentence down, she said she wishes to avail herself of the training opportunity.

So -- so, it's funny. It's a little bit almost hypocritical. If we interpret this -- and as I said, I don't know her and I don't want to speculate, but it seems like she is saying, listen, I'm concerned that there is a lot of problems, but, hey, if we are going to do a -- if we are going to get started on a trial, I want to avail myself of that training opportunity.

So, I don't know. It seems almost it's a little disingenuous to say you're concerned and

then say but I want to get started using it. So that's why, again, it is hard for me to interpret this.

Q. Was there any efficacy data when you began using that Prolift device in 2006?

A. There is never -- any new procedure we do, there is never any real good efficacy data on any new procedure.

Q. I want to go over some of the literature on the colporrhaphy and the efficacy, and I'm using -- I'm going to start with the Weber article that you cited in your report; and you are aware, Dr. Bales, that the Weber article from 2001 was re-analyzed with modern definitions of prolapse and success by Chmielewski, correct?

A. Yes.

Q. I'm curious why you cited the 2001 Weber article rather than the 2011.

A. So, I guess if that's a question, again, it's impossible to cite every article that's out there, so I picked certain ones.

MS. THOMPSON: And if you could mark this as Exhibit No. 8. I just have two copies of this, sorry.

(Bales Exhibit 8 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper, Dr. Bales?

A. Yes.

Q. And let's just go to the conclusions, and could you read the last paragraph for us.

A. Would you like me to read the entire last paragraph?

Q. Um-hmm?

A. Starting "In conclusion"?

Q. Um-hmm.

A. "In conclusion, this study provides further evidence that success after prolapse surgery depends heavily on the criteria that are used to define treatment success. In the frequently cited study by Weber, et al., when strict anatomic criteria were used, success was low. However, when contemporary, clinically relevant criteria for success were used, treatment success was considerably better, with only 11 percent of subjects experiencing anatomic recurrence beyond the hymen, 5 percent of subjects

experiencing symptomatic recurrence, and no subjects requiring surgery for recurrence or complications at one year.

"Given this and the excellent safety profile of traditional vaginal prolapse surgery, we conclude that anterior colporrhaphy that is performed in conjunction with other native tissue repairs is appropriate as a primary treatment of symptomatic anterior vaginal prolapse."

Q. And my question is, why did you cite the Weber paper in 2001 when this paper is more recent and more authoritative?

MR. MORIARTY: Objection, form and asked and answered. Go ahead.

Q. Well, let me just say, is your -- is your -- the reason that you didn't use this paper is you just can't cite everything? I think that was your answer before. Is that it --

A. Yeah --

Q. -- why you chose the old paper?

A. Yeah, I apologize. I chose -- I tried to choose a appropriate synopsis of a variety of different things. I'm sure there are other papers that I missed that might be more current or what

have you. But again, there is a lot of literature that's out there. I had to cite certain things.

Q. And you will certainly agree with me that a 5 percent symptomatic recurrence and no subjects requiring additional surgery is very different from the recurrence of 30 percent or more that you cite in your paper, right?

A. So you are asking if 30 is different than 5, and the answer is yes, 30 is different than 5.

Q. And you believe that you reported objectively on the success rates with colporrhaphy?

A. Yes. I think this paper, actually, this later information actually is somewhat of an anomaly; and I think most -- most papers and again, there is, you know, lots of data and lots of studies that aren't cited here, would suggest that the number is higher than 5 percent. And again, there is going to be a variety based on the paper.

Q. Okay. Well, let's go to one of the other papers that you cited and Fed Ex'd. I thought this one was apparently really important, and I just have two copies of this one, I'm sorry to say.

We will mark that as the next exhibit, 9, and you are familiar with this paper because you cite it in your paper, in your report, right?

A. Yeah. Peter --

MR. MORIARTY: It's so big you can hardly miss it.

MS. THOMPSON: The first paper was that -- I have two of these that are large size. The first one was from Duke. I thought they just thought it was from Duke that it was important.

THE WITNESS: These guys work with us. They are part of the University of Chicago now, Peter Sand and Roger Goldberg and Janet Tomezsko.

(Bales Exhibit 9 was marked for identification.)

BY MS. THOMPSON:

Q. I actually want to turn your attention to that discussion of this paper --

A. Okay.

Q. -- by Dr. Shull. Do you know Dr. Shull?

A. I don't.

Q. Have you seen Dr. Shull cited in Ethicon

documents frequently?

A. I think I'm familiar with that name. He is not a urologist; he is a urogynecologist. I think I have seen the name.

Q. And have you looked at his comment regarding Dr. Sand's paper, you will see that, I'm going to read to you from the comment, "They knew from their own experience as well as the experience of other surgeons that the use of nonabsorbable mesh is associated with an unacceptably high rate of complications. This is not surprising when one considers operating in a clean-contaminated field, the vagina."

And this paper used an absorbable mesh, correct, not polypropylene?

MR. MORIARTY: Objection, form. Go ahead.

A. Yeah, I guess I'm just -- you just read --

Q. Did this paper use absorbable mesh?

A. Yes, correct.

Q. Okay. And did Dr. Shull describe -- well, I'm going to read you something. Tell me if this is what the paper states. "In our most recent

series of over 300 women" --

MR. MORIARTY: I'm sorry. Can you please tell us what you are reading from?

MS. THOMPSON: Several factors are related to long-term outcome.

MR. MORIARTY: We need to know where you are reading from.

MS. THOMPSON: I'm telling you. In the comments section it says several factors are related to long-term outcome, and I'm reading from number one.

BY MS. THOMPSON:

Q. "In our most recent series of greater than 300 women in whom we specifically repaired the transverse portion of the pubocervical fascia, along with other defects, the rate of anterior compartment persistence or recurrence was 7 percent for prolapse halfway to the hymen and 2 percent for prolapse to the hymen. We used no mesh."

You will agree with me that a success rate of 7 percent halfway to the hymen and 2 percent for prolapse to the hymen with a native tissue repair is significantly less than the 30 percent that you cited in your expert report,

correct?

MR. MORIARTY: Objection, form.

A. I think 30 percent is a more accurate representation of what the experience is nationwide for sure, as you just read.

Dr. Shull is a very accomplished urogynecologist who I don't know personally, but he is citing his own work, and he obviously gets excellent results with his native tissue repair.

I'm not sure how long these patients were followed, but he cites 7 percent in his experience, and 7 percent is a lower number than 30 percent.

MS. THOMPSON: I've just handed another paper. Would you mark this as Exhibit No. 9.

MR. MORIARTY: 10.

(Bales Exhibit 10 was marked for identification.)

BY MS. THOMPSON:

Q. Dr. Bales, are you familiar with Exhibit 10, a paper by Funk and Visco?

A. Yes.

Q. And this paper looked at 27,809 anterior

prolapse surgeries. The 5-year risk of surgery for recurrent prolapse was similar between vaginal mesh and native tissue groups with 10.4 percent recurrent with mesh and 9.3 recurrent with native tissue. You will agree that those numbers are significantly less than the 30 percent that you cited in your expert report, correct?

A. Yes.

Q. And that there was -- in this paper of 27,000-plus patients, there was no difference between mesh and native tissue repairs, correct?

A. Yes, it looks like they are, right, essentially similar.

MS. THOMPSON: And Exhibit No. 11.

(Bales Exhibit 11 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper by Dr. Oversand?

A. Yes.

Q. And Dr. Oversand had a satisfaction rate of 94 percent of patients with native tissue anterior repairs and a 5-year reoperation rate of 2.6 percent in one group and 8.9 percent in the

other group and concluded that POP surgery using native tissue repair entails low reoperation rates with excellent subjective and objective results and should be the primary -- should be the first choice in treating primary POP providing use of adequate surgical technique as was published in 2013.

That's certainly different from what you cited in your expert report, correct?

MR. MORIARTY: Objection, form.

A. Again, the numbers are lower in this paper in terms of the recurrence rates, yes.

MS. THOMPSON: And Exhibit No. 12.

(Bales Exhibit 12 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper, Dr. Bales?

A. Yes.

Q. And this is the three-year followup on Dr. Iglesia's original Prolift study, correct?

A. Yes. I'm just trying to see if they are all Prolift people, to make sure on the methods.

Yes, okay.

Q. And you are aware that this study was

halted prematurely because of 15.6 percent mesh erosion rate which exceeded their predetermined limit, correct?

A. Yes, it is prematurely halted.

Q. And -- but they continued to follow the patients for efficacy, correct?

And these authors concluded that there was no difference in three-year cure rates when comparing patients undergoing traditional vaginal prolapse surgery without mesh with those undergoing vaginal colpopexy repair with mesh, correct?

A. Right. You can read their conclusion. They saw no difference.

Q. And this paper wasn't included in your expert report, was it?

A. I don't think so.

Q. And it is still your opinion that colporrhaphy has a recurrence of over 30 percent and that mesh repairs are preferable?

MR. MORIARTY: Objection, form.

A. It's my opinion that, yeah, anterior recurrence rates are as high as 30 percent.

Q. Or you said 30 percent or more, not as high as 30 percent.

A. As high as 30 percent or more than 30 percent.

Q. So your opinion is the recurrence, high rates of recurrence of 30 percent or more with colporrhaphy?

A. Yes. If you follow patients long enough, yes, I believe that's an accurate statement, even though there is certainly papers that we can tease out of the literature, as we are doing, that show the recurrence rate is lower.

Q. But you didn't mention any of those articles in your expert report, correct?

A. The bibliography on the expert report, as you've stated now several times, did not include every single paper in the literature.

Q. And I'm actually using many of your papers that you just took the information that was favorable to your opinions, correct?

A. I appreciate that very much, counsel.

Q. Correct?

A. Correct.

MS. THOMPSON: Another big one, Exhibit 13.

(Bales Exhibit 13 was marked for

identification.)

BY MS. THOMPSON:

Q. We are going to go to the next paragraph in your report.

MR. MORIARTY: Well, wait. Are you asking him about 13 or his report? Because I want to take a second to look at this.

MS. THOMPSON: Sure, go ahead. This is applicable to the next paragraph, but feel free to take a look at it.

And I didn't realize this article was highlighted. I apologize for that.

BY MS. THOMPSON:

Q. Dr. Bales, are you familiar with this paper from Duke published in 2000?

A. Yes.

Q. It's titled "Vaginal mesh erosion after abdominal sacrocolpopexy." In your last paragraph you say, "Due to the shortcomings associated with these native tissue surgical repairs, surgeons began using mesh for the treatment of POP. It started with the use of mesh in ASC. After that, in the 1990s, pelvic surgeons began to use mesh transvaginally, in order to take advantage of the

fewer complications which result from the use of that approach."

You didn't cite anything for that opinion that pelvic surgeons were using mesh transvaginally to take advantage of fewer complications. I wanted you to look at the Visco paper that did use mesh transvaginally, and Dr. Visco and his colleagues found an unacceptable rate of erosion when they used transvaginal mesh, correct?

MR. MORIARTY: Objection, form.

A. I think --

Q. I'm reading. "In conclusion, both abdominal sacral colpopexy and abdominal-only sacral colpoperineopexy appear to have a low and comparable rate of vaginal mesh erosion."

Their erosion rate was 5.5 percent overall, 3.2 percent in the abdominal sacrocolpopexy group.

"Vaginal placement of mesh results in an unacceptably high rate of mesh erosion and a shorter time to erosion than any other form of vault suspension in this study."

And these authors abandoned the use of

transvaginal mesh because of the high exposure rate, correct?

MR. MORIARTY: Objection, form.

A. The comparison here, though, was --

Q. Just answer my question. They abandoned the use of transvaginal mesh because of the high exposure rate, correct?

MR. MORIARTY: One of my objections was form because your question was several minutes long, so I'm not sure what the question was.

BY MS. THOMPSON:

Q. The question is short. These authors abandoned the use of transvaginal mesh because of the high complications rate, correct?

MR. MORIARTY: Objection.

A. Does it say it here? Does it say they abandoned it? I don't see that it says they write "we have abandoned use of mesh." So, I'm not sure how we -- and again, I'm not reading it. Did they say they've abandoned? If they say they have, then I guess we could take that at face value, but I'm not sure it says it here. So, why do you think they have abandoned it?

They are comparing it with the abdominal sacral colpopexy and they say that it is a higher rate of mesh erosion compared to the abdominal sacral colpopexy and the sacral colpoperineopexy, but I don't see anything about them abandoning anything.

Q. While I'm finding that, the authors thought that mesh erosions may be the only clinical manifestation of a bacterial contamination. If this is true, it supports our finding that the rate of mesh erosion was found to be higher in operations with vaginal mesh compared with those in which vaginal sutures were placed, and this may be explained by a greater exposure of the mesh material to the vaginal floor of the vaginal mesh group.

Did I read that correctly?

A. You read that exactly. You read -- those three sentences were exactly how it's stated here.

Q. And when was Gynemesh PS introduced to the market?

A. You will have to refresh my memory specifically. I don't remember the exact date.

Q. Was it 2002? Does that sound right?
A. That sounds right.
Q. I'm interested in your opinion on Page 5 that Prolift --
A. To clarify the sentence we just said, it looks like January 2002.
Q. And I'm reading your opinion. "The Gynecare Prolift pelvic floor system delivered pre-cut Gynecare Gynemesh PS polypropylene mesh to essentially recreate the normal anatomic pelvic floor."
Is it your opinion --
A. I apologize. Where on 5 is that? Just so I'm reading with you, where is it?
Q. "With this goal in mind" paragraph.
A. Okay. I got it.
Q. Is it your opinion that Prolift recreates the normal anatomic pelvic floor?
A. That's the goal. That's what we try to -- try to approximate. I don't think --
Q. Does Prolift recreate the normal anatomic pelvic floor?
A. Yes. That's -- you are attempting to do that. You are attempting to put everything back in

position and create the normal anatomy, that the bladder is back up in position, the enterocele is corrected and the rectocele, so yes, that's the goal.

Q. I didn't ask if that's the goal. I asked does Prolift recreate the normal anatomic --

A. Yes. And let me, I'm just going to add, there is no surgical procedure that everything then is a postoperative situation, so you can't take something that's virgin and do any kind of surgery on it and truly say that it's exactly the same. So, let's just make that clarification. So, you can make the anatomy normal, but it is still a postoperative situation. That's the only clarification I will add.

MS. THOMPSON: And I will object as nonresponsive.

Exhibit 14.

(Bales Exhibit 14 was marked for identification.)

BY MS. THOMPSON:

Q. Is this a document that you have seen, Dr. Bales?

A. If this date is correct, it was from

August 1998. I may have seen it. I can't say 100 percent.

Q. And this was prior to the introduction of Gynemesh PS for transvaginal use in prolapse, correct?

A. Yes, it looks that way.

Q. And if you will go to the introduction, will you read the second -- beginning in this response to this Gynemesh paragraph and then the bullet points underneath.

A. "In response to this Gynemesh, a Prolene (polypropylene) mesh for repair of anterior prolapse was launched in June. At this time it was recognized that Prolene is far from being the ideal material for this indication. However, it was decided that the Gynecare Division should launch this product for the following reasons: To raise awareness of the possibility of using a mesh for prolapse repair." Next bullet point, "To gain entry into this growing market before competitors; to spend time seeking out key surgeons as product champions and to allow time to carry out further market research into what the ideal product for this indication might be."

Q. Is there a bullet point about improving outcomes for patients?
A. No.
Q. Did Ethicon at this time have any information that Gynemesh would improve outcomes for patients?
A. I don't know.
Q. If they did, it certainly wasn't mentioned in this document, in the introduction of this document, correct?
A. It's not mentioned in the introduction of this document.
Q. Going to your discussion of the efficacy of Prolift in the anterior compartment you --
A. What page are we on?
Q. 5, going into 6.
A. Okay.
Q. You provide a chart listing some of the trials with polypropylene mesh and compared with native tissue repairs, correct?
A. Yes.
Q. And this chart only reflects anatomic cure in the anterior compartment, correct?
A. That's correct.

Q. And the author of the paper in which this chart was extracted is Dr. Jacquetin, right?
A. Yes, okay.
Q. And Dr. Jacquetin is a patent holder for Prolift, correct?
A. I don't know, I don't know.
Q. You don't know that Dr. Jacquetin and the TVM group?
A. I don't know him.
Q. Okay. Are you aware that Jacquetin is a consultant for Ethicon?
A. I know that name.
Q. It's your opinion -- I'm skipping over to Page 7 --
A. Page 7, okay.
Q. -- that the only unique risk with Prolift or Gynemesh PS is mesh exposure and erosion, which was well-known to surgeons. Is that your opinion?
A. Yes.
Q. That the only unique risk is exposure and erosion?
A. Unique risk.
MR. MORIARTY: We have been going an

hour and a half. Ready for a break?

MS. THOMPSON: Sure, take a break.

(Recess taken, 9:32 - 9:41 a.m.)

MS. THOMPSON: Back on.

BY MS. THOMPSON:

Q. I had asked earlier, Dr. Bales, your opinion that the only unique risk is mesh exposure and erosion, and for that opinion you cited the Abed paper from 2011, correct?

A. I did.

MS. THOMPSON: And we will mark this as Exhibit 15.

(Bales Exhibit 15 was marked for identification.)

BY MS. THOMPSON:

Q. And this paper is titled "Incidence and management of graft erosion, wound granulation and dyspareunia following vaginal prolapse repair with graft materials: a systematic review."

Why did you not include the dyspareunia that's discussed in this paper when you cited it as your support for the only unique risk with Prolift or Gynemesh PS is mesh exposure and erosion?

A. Well, that sentence is as stated. I'm

just discussing the unique risk associated with having the mesh, and you know, in other areas we talk about dyspareunia rates and the first paragraph discusses dyspareunia rates and such. So, I didn't include every part of this paper.

Q. Does this paper state that the only unique risk with Prolift or Gynemesh PS is exposure and erosion?

A. I don't know if that exact verbiage is used in this paper. I would have to refresh my memory.

Q. Well, obviously it wouldn't because it discusses graft erosion, wound granulation and dyspareunia following prolapse with graft materials, right?

A. Right, and my point in writing my report is that those other type complications can be seen with or without the presence of mesh, which is one of the reasons. Again, we describe the unique risk being the presence of the mesh and the exposure and the erosion, so I guess just to clarify that.

Q. But you have already said that the rates, the incidence, the severity, the permanence and responsiveness to treatment are all important

when you are talking about adverse events or complications, right?

A. Yes, it's all important.

Q. And at least in this review, the dyspareunia rate associated with graft materials was 9.1 percent, correct?

A. That's correct.

Q. We were talking also about Jacquetin, who is an Ethicon consultant, and I will represent to you that he is a patent holder on Prolift.

MR. MORIARTY: Is this one for me or is this the only one?

MS. THOMPSON: Some of these I just have two copies of, I apologize.

MR. MORIARTY: Are you marking it?

MS. THOMPSON: Yeah, I will go ahead and mark it.

THE WITNESS: So I guess we are up to 16.

(Bales Exhibit 16 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper, Doctor --

A. Yes.

Q. -- Bales? And actually, which did I give you?

A. You have too many papers.

Q. I do. I actually meant to give you a different one, but we will go ahead and talk about this one. This is a paper, the 2013 --

A. 2009.

Q. This is the 2010 Jacquetin paper, the three-year followup.

And you will agree with me, in this paper the anatomical failure rate was 20 percent at three years, correct, in the results section?

A. Correct. You are reading right from the paper.

Q. Yep. And Dr. Jacquetin found that, listing results of the abstract summary, correct, listed that or stated that a significant number of patients, 41 percent, ceased sexual activity by three years, correct?

A. That's what his results were.

Q. And that de novo dyspareunia was reported by 8.8 percent, correct?

A. Correct.

Q. And that would be consistent also with the paper we just looked at previously, at the Abed paper, correct?

MR. MORIARTY: Objection. Are you just talking about the dyspareunia rate?

MS. THOMPSON: Just the dyspareunia. Sorry.

A. Yes.

Q. If we go to the Jacquetin 2013 paper -- we will mark this one too, 17. I think you are familiar with this one because it is cited in your expert report, correct?

A. Correct.

(Bales Exhibit 17 was marked for identification.)

BY MS. THOMPSON:

Q. And this Jacquetin paper with the followup of the TVM, total transvaginal mesh series, this is the one that your chart was derived from, correct?

A. Yes.

Q. And in this paper, in the results section of the abstract, Dr. Jacquetin reports 16 percent with mesh exposure for which 8 resections

needed to be performed, 7 exposures still ongoing at the 5-year endpoint, all asymptomatic, correct? I'm reading that correctly?

A. You are reading that correctly, yes.

Q. And only 33 out of 61, 54 percent, sexually active patients at baseline remained so at 5 years in his study, correct?

A. That's correct.

Q. And de novo dyspareunia was reported by 10 percent, correct?

A. That's correct.

Q. And you are aware that Jacquetin also published a paper based on the experience titled "Complications of Vaginal Mesh"?

A. Do you have it? Did you want to go over it?

Q. I need a helper.

A. Maybe this young fella.

MS. THOMPSON: It is just a short paper. I do have one additional copy, and we will mark that as Exhibit 18.

(Bales Exhibit 18 was marked for identification.)

BY MS. THOMPSON:

Q. Do you need a moment to look at that, or are you familiar with this paper?

A. Yeah, I'm familiar. I'm skimming it over, but if I need more time I won't answer your question and I will ask for a few more minutes, but you can ask your question.

Q. This paper is based on Jacquetin's experience with removal of 160 explant -- implants, correct?

A. I will need just a second to confirm that number.

Yeah, I mean, it seems that he is just discussing more broadly everything about some of his experiences and citing some other work, but then on Page 895 he discusses that the French experience is 160 implants that were removed by his group, yep.

Q. And under the complications he lists infections, correct, on Page 894?

A. Correct.

Q. And he lists exposures and erosions, correct?

A. Yep.

Q. And he lists retractions, correct?

A. That's correct. We are reading, yes, those are the three things.

Q. And he describes the average shrinking of 25 to 30 percent in experimental surgery, and it may reach 40 percent of the initial surface of the implant in patients after surgery.

MR. MORIARTY: Is that a question?

Q. And therefore, many surgeons will use large implants to cover defects and anticipate scarring, shrinkage and puckering. Is that what Dr. Jacquetin describes in this paper?

MR. MORIARTY: Objection, form.

Q. Did I read it correctly?

A. I think that bullet point you read exactly, so that's what he has written here, yeah.

Q. And we will talk about your opinions on shrinkage in a minute, but at least Dr. Jacquetin listed that retraction as a complication of the mesh devices he studied, correct?

A. Sure, and you left out -- right, and he describes on a rat's abdominal wall and then he is guesstimating based -- he says it may reach 40 percent on patients. So, it sounds like at

least on the experimental side it's on the rat's abdominal wall, but you read the rest of the sentence accurately.

Q. So, you think when he says -- sorry. So, you think when he says, therefore, many surgeons will use large implants to cover defects and anticipate scarring, shrinkage and puckering he is talking about rat surgeons?

MR. MORIARTY: Objection, form.

MS. THOMPSON: Well, I'm just asking if that's what he meant, what he said.

MR. MORIARTY: You asked him if you read that exactly, and you didn't. You skipped the part about the rats, so he was just pointing out what you skipped.

MS. THOMPSON: I don't think I did.

MR. MORIARTY: That's why I objected to form. You skipped the part about the rats.

MS. THOMPSON: Well, I didn't intend to skip.

BY MS. THOMPSON:

Q. You don't think the second sentence is applying to rats, do you, Dr. Bales?

A. Well, the second sentence specifically

says patients; the first sentence definitely says rats. So, I guess that was the only clarification.

Q. So you think the 40 percent would refer to patients, human patients, right?

A. Well, again, I mean, he is not citing any specific study here. It sounds like he is surmising it may reach. I don't --

Q. But he is talking about humans, right?

A. He says in patients, so I would assume that means patients.

Q. And when he says many surgeons will use large implants to cover defect and anticipate scarring, shrinking and puckering, he is talking about human patients also; agree?

A. I suspect, although again, it's a very general statement, and I'm not sure which surgeons he is referring to or anything, how large. I mean, it's just kind of a very general statement. I imagine he is referring to surgeons operating on humans. I don't want to over-infer.

Q. Okay. I want appreciate that.

(Mr. Jake Plattenberger entered the deposition proceedings.)

MR. MORIARTY: Can we help you?

MR. DAVIS: He is with me.

BY MS. THOMPSON:

Q. Going back to your report, Dr. Bales, on page -- the bottom of Page 7, let's go to Page 7, in the first paragraph, dyspareunia rates were very acceptable. What is an acceptable dyspareunia rate for you following any type of surgery?

A. Well, obviously, it would be better certainly for patients not to have dyspareunia, but any -- I guess we all have a different opinion.

I'd tell you my opinion would be any type of vaginal surgery we are doing, if we are getting dyspareunia rates under 10 percent, it's probably very acceptable. But again, that's very sort of general, and again, a lot of patients, as we just cited on some of the previous studies, don't remain sexual active. A fair majority of the patients aren't sexual active.

But to answer your question, I guess anywhere in the low teens to less than 10 percent would be acceptable for a vaginal surgical procedure like this.

Q. And you would agree that there is a likelihood that at least some of those patients who

are no longer sexually active and are not included in the study are not sexually active because of pain, correct, for whatever reason?

A. It could be. It's hard to say.

Q. But it would be reasonable to assume that, correct?

A. I don't like to assume, but for whatever reason, patients sometimes aren't sexually active.

Q. Become not sexually active after Prolift, correct?

A. Sure. The studies bear that out.

MS. THOMPSON: Number 19.

(Bales Exhibit 19 was marked for identification.)

BY MS. THOMPSON:

Q. And this is the Lowman paper that you cited in your report, correct?

A. Yep.

Q. And Dr. Lowman looked specifically at dyspareunia with Prolift, correct?

MR. MORIARTY: Objection.

Q. Well, the title is "Does the Prolift system cause dyspareunia," correct?

A. Yeah. This was, it looks like, a chart

review. They went back, and they were trying to assess dyspareunia rates.

Q. And Dr. Lowman is a consultant for Ethicon; would you agree with that?

A. I have no knowledge of him being a consultant of Ethicon. He may or may not be.

Q. I believe it is a she.

A. A she. "Joy" is probably a better female name, so I should --

Q. Or maybe it's not. I'm not sure.

And Dr. Lowman has a chart on Page 707e4 that lists the rates after various pelvic organ prolapse procedures of de novo dyspareunia, correct?

A. Sure. Which chart is it, which one?

Q. Page 707e4.

A. Table 4, I got it. Table 4, you mean?

Q. Correct. And did you go back and look at these articles to see if those numbers were correct?

A. To see what numbers are correct?

Q. The numbers that she provided in this table for the other procedures.

A. Did I recheck her work?

Q. Did you look at the articles that she cited in Table 4?

A. So, when I read over the articles, I don't always look at all the cited articles within -- that are embedded within the article. Sometimes I do and sometimes they were previously cited and are in part of the list.

Q. So the answer is no. I mean, that's okay. Did you look at the articles that were cited in Table 4?

A. Yeah. I don't remember looking at each and every one, but I may have skimmed through them and I may have.

Q. Well, let's just look at one of them, the Weber paper on anterior/posterior colporrhaphy. Okay?

A. Okay. Whatever you want.

MS. THOMPSON: And that's Exhibit 20.

(Bales Exhibit 20 was marked for identification.)

BY MS. THOMPSON:

Q. And this study cited by Dr. Lowman in her paper looks at sexual function after native tissue prolapse repairs, correct?

A. Yes. I mean, it looks at sexual function and vaginal anatomy, assessing sort of both those things, vaginal dimensions and such.

Q. And Dr. Weber looked at dyspareunia before and after surgeries, correct?

A. Yes. It's a questionnaire, obviously, right? You don't see that. You ask the patients, and it looked like patients reported preoperatively and then postoperatively.

Q. And are you aware that in this paper dyspareunia was persistent in only one of the 14 women?

MR. MORIARTY: Objection.

Q. You can go ahead and look at the paper if you want to. I'm reading dyspareunia was persistent in one woman on Page 1612.

A. Yeah, I mean in the interest of time, I mean, it would be nice to study this a little more closely, but it looks like there were six patients who on their preoperative questionnaire had dyspareunia, and one of those six postoperatively -- again, these were the patients who reported dyspareunia preoperatively -- one of the six it was maintained, persisted.

Q. And if you use that statistic, 1 out of 75 would be 1.3 percent, correct?

MR. MORIARTY: Objection. Go ahead.

A. One out of 75 is 1.3 percent?

Q. Correct.

A. Yeah, that's mathematically correct.

Q. So would you agree with me that Dr. Lowman saying that the dyspareunia rate of 19 point -- 19.0 percent is really accurate?

MR. MORIARTY: Objection, form.

A. Where did you get the 75 a moment ago?

Q. There is 75 patients in the study. Dr. Lowman says 14 of 75 have de novo post-op dyspareunia. What she doesn't mention, that only one of those had persistent dyspareunia, correct?

A. Yeah, but it developed it, so 14 had new dyspareunia.

Q. But all resolved spontaneously, correct, except for one?

MR. MORIARTY: Objection.

A. Well, there was only 6. Of those 6 patients, 5 of the 6, so at least in this study, they apparently resolved.

Q. Okay. So only 1 out of 75 ended up with

persistent dyspareunia, correct, after native tissue repairs?

A. Well, not really. You are comparing apples and oranges. I mean, the first group, it's a different subset of patients. If you report the 6 who had dyspareunia beforehand, so in that group 5 out of 6, which is about 83 percent, resolved; 1 out of 6, so 16.66 percent, persisted.

So, if you look at that subset, and then it's apples and oranges, you can't lump them all together. The patients who didn't have dyspareunia, then you can look at their dyspareunia rates after surgery, but I don't think it's fair to use the -- you are mixing up the numerator and the denominator there, I think.

Q. I am looking at Dr. Lowman who says that 14 of the 75 patients in Dr. Weber's study had de novo post-op dyspareunia. I'm just saying how many of those patients had persistent dyspareunia.

A. Well, yes, those --

Q. Out of 75 according to Dr. Lowman?

A. Correct. So, it looks like 14 out of 75, it was not persistent. It started after the procedure, yes, I would agree with that, if that's

what you are saying.

Q. Persistent doesn't mean it starts after the procedure. Persistent means it lasts beyond the term of the study, correct?

A. Well, in this and how it's used here is the dyspareunia that was present before the surgery, that's the persistence that Dr. Weber is talking about in this paper.

Q. Okay. It says, reading from Page 1611, "With dyspareunia defined as pain with sexual activity occurring usually or always, the prevalence was 8 percent before surgery, 6 of 80 women, and 19 percent after surgery, 15 of 80. Dyspareunia was persistent in one woman, developed as a new symptom in 14 and resolved in 5."

So, Dr. Lowman's numbers of 19 -- or 14 out of 75 are incorrect, right?

MR. MORIARTY: Objection.

A. No. How is that incorrect? That's exactly what's reported here.

Q. We will just disagree on that one.

A. I mean, de novo means it started, so it developed in 14, 14 in the 75. That's what's reported there. But I'm happy to disagree. If you

want to agree to disagree, that's fine, but I think those numbers are exactly right.

Q. Is it your opinion that the dyspareunia that's known to occur with vaginal mesh procedures is no different from dyspareunia that occurs in native tissue repairs in regards to rates, severity, permanence and responsiveness to treatment?

MR. MORIARTY: Objection to form.

A. Can we repeat that back, please? I'm sorry.

Q. Is it your opinion that the dyspareunia that occurs with mesh repairs as reported in the literature is no different from dyspareunia occurring after native tissue repairs when you consider rates, severity, responsiveness to treatment and permanence?

MR. MORIARTY: Objection, form. Go ahead.

A. Yeah, I don't think there is a tremendous difference. I think dyspareunia is dyspareunia, and it's very hard to quantitate dyspareunia. To some degree we attempt to in some of these studies, but on balance I think they are

similar.

Q. Your opinion is dyspareunia is dyspareunia?

A. Well, dyspareunia just means pain with intercourse, and I think it's very hard to quantitate pain with intercourse, so that's what I'm implying.

Q. You don't think there is a difference between some irritation that might occur with vaginal atrophy and women who have pain that's so severe that they will be in bed for three days afterwards with pain or are unable to even attempt sex? Are those equivalent to you?

MR. MORIARTY: Object form.

A. So -- so -- so --

Q. Are those equivalent to you?

MR. MORIARTY: He is trying to answer your question.

A. Let me clarify. Again, dyspareunia is historically very difficult for us to quantify. It is without -- obviously, you make a very simple analogy. Of course a woman who has very mild pain is not the same as a woman who has, you know, horrific pain with intercourse.

So, there is a scale, of course, but my point was when you are trying to compare and discern whether it's from associated with a hysterectomy or a native tissue repair or a mesh, I think on balance those can be the same. And that was the question you asked me. You didn't ask me is dyspareunia from patient to patient exactly the same.

Q. But you answered dyspareunia is dyspareunia.

A. Meaning, again, that -- let me clarify that. Dyspareunia needs to be taken seriously, and that's my only point, that when dyspareunia occurs, it's something that if a person has pain with intercourse, we need to take that seriously.

So, I don't -- I don't say, oh, it's mild or major. Dyspareunia is a serious problem for a woman, and that's why if you have dyspareunia, it's bad and it's something we will try to correct. That's the point I was trying to make, and I probably didn't answer it very articulately.

Q. Dyspareunia may not always be bad; some dyspareunia is very easy to treat, correct?

A. Yes, but it's still bad. It may be easy to treat, but it doesn't mean it's not bad.

Q. Do women with vaginal atrophy ever have severe, horrific vaginal pain with intercourse?

MR. MORIARTY: Object.

A. Yes.

Q. That cannot be treated easily with local estrogen therapy?

A. That's the first thing we do with those patients with atrophic changes, and very often that can solve the problem, but not always.

Q. Do you treat women with dyspareunia that don't have a urologic source?

A. Yes.

Q. You treat women with atrophic vaginitis when that's the only condition they are presenting with?

A. Yeah. So, they typically would come see me because maybe they had a kidney stone or they have had a urinary tract infection, and then in taking their history we find out they also have dyspareunia. We do a vaginal exam, and if they have atrophic vaginitis, of course we treat it.

That's part of our history-taking and

thorough physical exam. There is no urologic cause for dyspareunia. I mean, bladder pain and dyspareunia are slightly distinct, right, so dyspareunia --

Q. Or postoperative urologic surgery?

A. Correct.

Q. So, your opinion that the quality of dyspareunia and vaginal pain that occurs after mesh surgery is no different from that that can occur with other prolapse surgery?

A. Yes. It may not be any different at all.

Q. And you are ignoring the dozens of articles that would say something differently, correct?

MR. MORIARTY: Objection, form. Go ahead. It's argumentative.

A. I'm not sure they say anything a whole lot differently. There is papers that cite pain and dyspareunia after any type of vaginal surgeries and stuff; and certainly among those, as you stated earlier, are papers now looking at experiences with vaginal mesh procedures.

Q. Can you cite any paper that would

support your opinion that the pain associated with vaginal mesh is no different -- and we are considering all the factors, not that just that it occurs. Can you cite any paper that says that pain that occurs after mesh procedure is no different from that occurring with any other native tissue repairs?

A. I'm not sure there has been a comparative study, so I can't say that.

Q. It doesn't even have to be a comparative study. Has anybody offered an opinion that the mesh pain after mesh surgery is no different when you consider all the factors that we have talked about, the native tissue repairs?

MR. MORIARTY: Objection. Go ahead.

A. So, if I see a patient who has vaginal pain and fibromyalgias and says she can't get near her husband and she is on the verge of divorce and she is coming to see me because she was told I'm a pelvic floor reconstructive guy and what can I offer her and that woman has never had vaginal mesh surgery, any surgery, and she has horrific dyspareunia that's affecting her marriage, that woman's dyspareunia is no different than a patient

who has had mesh and comes in and complains of the exact same pain.

Q. How many postmenopausal women do you see with new onset of dyspareunia due to pelvic floor myalgia?

A. That would be hard for me to quantitate the number. A fair number.

Q. When was the last time you saw someone, new onset, menopausal, pelvic floor myalgia, horrific dyspareunia, in your practice?

A. Probably Monday.

Q. I would like to see her records.

MR. MORIARTY: Motion to strike.

Q. You cited the Maher Cochrane reviews on pelvic organ prolapse repairs in your paper?

MR. MORIARTY: Are you talking about in his report?

MS. THOMPSON: In his report, sorry, in your report, and the Cochrane 2016 review of pelvic organ prolapse, and we can go ahead and mark this.

(Bales Exhibit 21 was marked for identification.)

BY MS. THOMPSON:

Q. And I'm just giving you the summary of the review, and let's look at the key results. The Cochrane review 2016 states that overall the quality of the evidence ranged from very low to moderate. The main limitations were poor reporting of study methods, inconsistency and imprecision, correct?

MR. MORIARTY: I'm sorry. I hate to stop you. Could you tell me exactly where you are reading? Obviously you are on the last page.

MS. THOMPSON: The very last sentence of the last page.

MR. MORIARTY: Oh, you are under main results. I thought you said under key results.

MS. THOMPSON: That what I was reading was just quality of the evidence on the last page.

BY MS. THOMPSON:

Q. Did I read that correctly, Dr. Bales?

A. Yeah, I'm sorry. I was on Page 2. I was reading under main results.

Q. Under quality of the evidence on Page 3, "Overall the quality of evidence ranged from very low to moderate. The main limitations were poor reporting of study methods, inconsistency and imprecision." Did I read that correctly?

MR. MORIARTY: I object. I don't know where you are, what you are reading. I don't see a section called quality --

MS. THOMPSON: Plain language summary on the very last page.

MR. MORIARTY: Okay. So you are on the fourth page of this document under now "Quality of Evidence" at the very end?

MS. THOMPSON: That's where I have been the whole time.

BY MS. THOMPSON:

Q. "Overall, the quality of the evidence ranged from very low to moderate. The main limitations were poor reporting of study methods, inconsistency and imprecision."

Did I read that correctly?

A. Yes.

Q. And did the authors conclude -- I'm back on the previous page on author's conclusions.

"The authors conclude that the risk/benefit profile means that transvaginal mesh has limited utility in primary surgery. While it is possible that in women with higher risk of recurrence the benefits may outweigh the risk, there is currently no evidence to support this position."

Did I read that correctly?

A. You read it perfectly.

Q. And in the last paragraph, "In 2011, many transvaginal permanent meshes were voluntarily withdrawn from the market and the newer lightweight transvaginal permanent meshes still available had not been evaluated within an RCT. In the meantime, these newer transvaginal meshes should be utilized under the discretion of the ethics committee."

Did I read that correctly?

A. Yes. You read it fine.

Q. In 2016 the authors of the Cochrane study, with Prolift having been on the market for 11 years and Gynemesh on the market for 16 years, are stating that these meshes should only be utilized under the discretion of an ethics committee, correct?

MR. MORIARTY: Objection.

Q. Is that not what the authors concluded?

A. The authors' conclusion says as you read them. They state new or transvaginal meshes should be utilized under the discretion of the ethics committee. That's what's written here. And it's 14 years with the Gynemesh, 2002 to 2016, 14 years.

Q. What did I say?

A. 16.

Q. I stand corrected.

MR. MORIARTY: And you said like 11 to 12 for Prolift.

MS. THOMPSON: Well, it was introduced in 2005, so that would be 11.

MR. MORIARTY: And taken off the market in 2012.

MS. THOMPSON: I intended to say 11 years after it was introduced to the market. If I said 11 years of use, I am mistaken. There are certainly women who have had it for 11 years.

We will mark this next as 22.

(Bales Exhibit 22 was marked for identification.)

MS. THOMPSON: I just have one copy of this.

BY MS. THOMPSON:

Q. And this is a paper by the same author, Maher.

A. Same author; what do you mean, same author?

Q. As the Cochrane review.

A. Yes, okay.

Q. And going to Page 4 of this article, peer-reviewed article --

A. Yes, ma'am.

Q. These are the authors of the Cochrane review that you cited in your paper, state the data on transvaginal -- first of all, when was this published?

A. It looks like it was September 2013.

Q. The authors state the data on transvaginal mesh --

A. Can we clarify where on the page are you reading?

Q. Page 4 of 8 at the top of page.

A. At the top, okay. After "FDA 2011"?

Q. "The data on transvaginal mesh

outcomes" --

A. Yes.

Q. -- "from these systematic reviews are not as reassuring for the safety and efficacy of transvaginal mesh as data presented from initial case reports published by authors with a financial COI..."

That means conflict of interest, right?

MR. MORIARTY: Objection, form.

A. That's what conflict of interest --

Q. Does "COI" mean conflict of interest in this context?

A. Yes.

Q. "...with the product being evaluated."

Did I read that correctly?

A. Yes.

Q. And then it discusses the FDA 2011 transvaginal mesh alert. You are familiar with that document, correct?

A. Correct.

Q. And it says, "Unfortunately," reading that paragraph that starts, "Unfortunately, much of the current data on POP surgery presented in our systematic reviews fails to allay concerns outlined

in the September 2011 FDA transvaginal polypropylene mesh report that found the safety of transvaginal meshes has not been established; depending on the compartment, the efficacy of transvaginal meshes has not been established to be more effective than traditional repairs; vaginal mesh from POP repair should be reclassified from class II to class III to ensure premarket analysis includes a non-mesh control arm; currently marketed vaginal mesh products should undergo premarket evaluation to better explain" --

A. Postmarket.

Q. Sorry. Thank you.

-- "postmarket evaluation to better explain the risk/benefit of mesh versus POP repair without mesh; and safety and efficacy of mesh at sacral colpopexy had been established."

Do you disagree with these conclusions made by Maher, the author of the Cochrane reviews on prolapse mesh use?

A. Which specific ones? The entire --

Q. The ones I just read from this paper.

MR. MORIARTY: Objection, form. Go ahead.

A. Yeah, I have some disagreements on some of them. I mean, basically, if you want, we can go over them one by one. There is five bullet points.

The safety of transvaginal meshes has not been established. Well, there has been a wealth of studies on transvaginal meshes. We have been talking about them in a number of the studies. So, I think the safety has been established, and we could argue about, you know, each of the papers, but there is a lot of data out there, so --

Q. So, you disagree, that the safety has been established. You disagree with the authors of this paper and the Cochrane reviews, correct?

A. That's a different question. I thought we were talking about this right now.

Q. Well, I'm just saying since that's their opinion in this paper, you would disagree with the authors on that point, correct?

MR. MORIARTY: Objection, asked and answered.

A. Yes. I thought we would go point by point.

Q. And so you would disagree with the FDA as well on that point, correct?

A. No. I think -- well, the FDA report was from 2011, and I think the FDA report in 2011 just acknowledged that it was still early; and as you know, with that FDA report, it's cited that there is a variety of different complications that we need to be aware of. And to specifically this says the safety has not been established, I mean, yes, I would disagree. If you have a lot of patients and a lot of experience on safety, then to some degree I would disagree; I think it has been established. I think you have studies out there.

Q. And do you disagree that depending -- the second bullet.

A. Well, let's go through it. "Depending on the compartment the efficacy of transvaginal meshes has not been established to be more effective than traditional repairs." I think there is still, you know, better studies that need to occur, but for sure there is conflicting results on the effectiveness and whether transvaginal meshes are better. I would be fine with that, so, and as it says, depending on the compartment there is a lot of factors that, you know, like what specific, whether you are doing rectocele, cystoceles, what

have you.

Vaginal mesh repairs --

Q. Another point. But you will agree with me, there is no studies that establish superiority of vaginal mesh for effectiveness in the posterior or apical compartments?

MR. MORIARTY: Objection. Go ahead.

A. Yeah, there is not a lot of good head-to head studies that suggest it's superior.

Q. Are there any?

A. There are studies that suggest it's equivalent.

Q. Not superior?

A. Not superior. "Vaginal mesh for pelvic organ prolapse repair should be reclassified." Again, I don't -- you know, that's sort of not my area of knowledge base in terms of what goes into the classification scheme, if you will, so I don't have a good opinion on that.

"Currently marketed vaginal mesh products should undergo a postmarket evaluation," that's okay, I mean, but I don't have a strong opinion of that one way or the other.

And the last bullet point, "Safety and

efficacy of mesh at sacral colpopexy had been established." As we stated, I mean, again, there is a lot of data on sacral colpopexy, so I would agree that has been established, but as I said, I also would agree that the first point, there is at least data now that has established to some degree the safety and efficacy.

So, I hope that was clear. I just wanted to make sure you understood sort of --

Q. Were there any studies when Prolift was introduced in 2005 establishing safety and efficacy of the device?

A. Well, it was a new device, so I'm not aware that again it was being trialed and such, so...

Q. So the answer would be no?

A. So, no.

Q. And finally, are you familiar with this paper?

MS. THOMPSON: And we will mark that as Exhibit 23.

(Exhibit 23 was marked for identification.)

BY MS. THOMPSON:

Q. Are you familiar with this paper titled "Vaginal Mesh Contraction, Definition, Clinical Presentation and Management"?

A. Yes.

Q. And one of the two authors of this paper is also the author of the Cochrane reviews that you cited in your paper as well?

A. Maher.

Q. Maher. Is it your opinion that vaginal mesh contraction is not unique to vaginal mesh devices?

A. It is not -- say that again.

Q. You've given the opinion that the only complication unique to vaginal mesh devices is exposure and erosion, and I'm asking you is vaginal mesh contraction not unique to vaginal mesh devices?

A. I guess anything having to do with the mesh itself is unique to the mesh. We could argue about the extent of contracture, if you will. But if the mesh changes at all, it's only going to change if the mesh is present. So, again, I'm not sure that's a complication, but it's a behavior of

the mesh. Maybe that's more accurate.

Q. Vaginal mesh contraction characterized by severe vaginal pain, aggravated by movement, dyspareunia in all sexually active women and focal tenderness over contracted portions of the mesh on vaginal examination, commonly involving the lateral fixation arms, you have a question about whether that's a complication or not?

A. I don't have a question. If the pain exists, I have a question how much is specifically due to contracture, which is what you were just talking about.

Q. Well, these authors are reporting vaginal mesh contraction. Do you question their report?

A. I mean, their report is their report.

Q. And it certainly wasn't included in your expert report, was it?

A. It was not.

Q. Vaginal mesh contraction characterized by severe vaginal pain, dyspareunia in all women and focal tenderness over contraction. In fact, you say it's not even established that mesh contracts to any clinical significant degree;

correct?

A. That's what I said.

Q. You certainly consider vaginal mesh contraction a significant clinical condition, correct?

MR. MORIARTY: Objection. Go ahead.

A. I guess that we can argue about how much and how relevant contracture, how much it occurs, how well it's measured, and if that truly is clinically significant. Certainly these authors feel that they felt some of the pain that they are seeing is related to contracture.

Q. And you are aware that there are dozens, literally, of articles describing mesh contracture and the clinical symptoms, primarily pain, associated with it, correct?

A. I'm aware that both those things exist, and I'm certainly aware that mesh contractures occur, just like mesh contractures occur in inguinal hernias and ventral hernia and whatever, yes.

Q. Okay. We are talking about vaginal mesh contractions, right?

A. Yes, and I'm aware that they contract a

little bit.

Q. A little bit?

A. Well, I don't think it's certain. It's very unclear how much they contract. It hasn't been -- it's not well-studied, in percentages and things like that. But yes, that we can say it's safe to say vaginal meshes can contract. I will certainly agree to that.

Q. Okay. Well, you state in your report, and I'm just questioning whether this is objective and unbiased, that there is no medical literature conclusively establishing that mesh contracts with vaginal use to clinically significant degrees.

So, Maher's paper is not conclusive to you that it occurs?

MR. MORIARTY: Objection, form. Go ahead.

A. Again, there is two different points you are saying there. We are saying that --

Q. I first read your statement and then I want to --

MR. MORIARTY: Don't cut him off. He needs to answer your question.

MS. THOMPSON: I apologize.

MR. MORIARTY: If you don't like the answer, you can follow up.

MS. THOMPSON: I'm just trying to get through because I have three hours to cover about 12 products.

THE WITNESS: It contracts.

MR. MORIARTY: Three, I believe.

MS. THOMPSON: Anterior, posterior, total, six, seven, eight.

MR. MORIARTY: Prolift, Gynemesh PS.

MS. THOMPSON: Prolift, anterior, posterior, total, which he said was three different products, Plus M. Well, okay. That's three products that would give me seven hours. Okay. Go ahead.

A. That meshes, and we are talking about vaginal meshes, contract, to the extent of their clinical relevance, I guess I'm not -- I'm not -- I'm not convinced that we have a good understanding of the clinical relevance.

Q. So in the literally dozens of papers that talk about contraction, retraction, shrinkage, you are not convinced that that's a clinically significant condition?

A. I'm not convinced that in all those patients it's simply -- it's as simple as saying a little contraction occurred, and that's what's causing all the pain. I think that it's not very well defined. That's my opinion.

Q. Okay. The one paper you did out of the literally dozens of papers that discussed this, including the FDA, as a clinically significant condition that is unique to mesh, the one paper you selected to include in your expert report is Dietz. My question is --

A. So you are happy with this one, that I included this one?

Q. Oh, let's talk about this one.

A. Okay. Please.

Q. Did you find this paper on your own or were --

MR. MORIARTY: Is this marked?

MS. THOMPSON: Let's mark that as the exhibit next.

(Bales Exhibit 24 was marked for identification.)

BY MS. THOMPSON:

Q. My question, first of all, is this a

paper you found on your own literature search, or was this something that was furnished to you by defense counsel?

A. I don't recall. I think I found it on my own.

Q. And this is the one you chose out of dozens, if not hundreds, of articles that discuss mesh shrinkage, contraction, retraction and the clinical significance, correct?

MR. MORIARTY: Objection, form.

A. This is one that's cited in my Herrera report.

Q. Let's look at this report from 2011. You are aware that Dr. Dietz is a consultant for mesh manufacturers, correct?

A. Yes. Well, I'm just reading it. Actually, I didn't remember that, but I'm reading underneath on the first page here. It says he has acted as a consultant for various vendors, so yes, I guess he is.

Q. And Dr. Dietz used translabial ultrasound in this study, correct?

A. Correct.

Q. Wouldn't that transvaginal ultrasound be

more accurate in assessing mesh in the pelvic floor?

A. You know, I don't do translabial ultrasounds, so I'm not sure how well it penetrates to be able to assess it. I'm assuming that whether it is translabial or transvaginal, they were able to get dimensions, but I don't know enough about translabial ultrasound.

Q. Aren't most of the papers that you've seen or have you seen any looking at ultrasound to assess mesh shrinkage using transvaginal ultrasound?

A. Yes. Loyola has published some papers here in Chicago, Dr. Mueller. So, yes, I'm aware of that technique, and there has been some reports on that.

Q. And Dr. Dietz did the first scan in his paper at a minimum of three months, so the first scan was done three months following the placement of the surgery -- the placement of the mesh, correct?

A. It looks like the study design, it was between 3 and 52 months.

Q. And it's true that folding, wrinkling,

crumpling of mesh is often the explanation for the phenomenon of mesh contraction, correct?

A. So it folds and that causes the contractures? Repeat the question.

Q. Is it you are not aware of the folding and wrinkling of the mesh causing the reduction in size of the mesh tissue complex? You are not aware of that phenomenon?

A. I'm not aware that a fold then causes it to contract per se, no.

Q. But at three months, you will agree with me that the mesh is already encased in tissue or scar, correct?

A. Yeah. It might still be going on to some degree. I mean, obviously it's an evolving process and there might still be scar tissue being laid down.

Q. But you will agree with me if you are looking at mesh shrinkage, you don't start after three months; you start at when the device was placed because the majority of the shrinkage is going to occur before implant of tissue, correct?

A. I don't know that. I don't know if we know that.

Q. So you don't know that, all right.
A. I don't know if anybody knows that.
Q. Let's look at the results.
A. That's why this study was being done.
Q. Okay. Let's look at the results.
18 of 40 at this followup, 45 percent, considered themselves cured. Are those good results?
A. Can I find where you said what specifically the -- in the results?
Q. 18 on Page e3, 18 of 40 considered themselves cured at this followup, 45 percent. Are those good results for outcomes?
MR. MORIARTY: Objection, form.
Q. Are those good results?
A. That sentence reads 18 to 40 considered themselves cured and 18 of 40 felt improved, so if 36 out of 40 felt cured or improved, that's pretty good results.
Q. I asked about 18 of 40 considered themselves cured; is that a good result?
MR. MORIARTY: Objection.
A. Well, you can't -- you can't -- you can't ask it like that, counselor.

Q. I can ask it any way I want to, Dr. Bales.

A. True.

Q. I was going to ask you about the 18 out of 40 later that felt improved, but 18 of 40 consider themselves cured; would you consider that a good result?

MR. MORIARTY: Objection, asked and answered.

MS. THOMPSON: Okay. We will just take your answer then.

A. Don't you see, if 18 of the 40 were cured and everybody else was worse, that wouldn't be a good result, but if 18 out of 40 are cured and another 18 are improved, that's 36 are cured or improved.

I don't know what the scale they were using, so that's funny you are asking me these questions that are sort of taken out of context. I can't give a simple yes-or-no answer. So, I think it is important. I guess you want it to be accurate, right? You want my responses to be accurate, so we should -- we should -- we should probably allow me to explain.

Q. Okay. So let's clarify this a little bit. The objective prolapse recurrence rate, 16 of 40, 40 percent, in this study, would that be a good result? Objective prolapse recurrence, 40 percent in this study, correct?

A. Correct.

Q. Subjective recurrent lump, 27.6 percent, correct?

A. 2.5 times 11, okay. Yes, that's what they are reporting.

Q. And the authors state that folding or warping of the mesh during or immediately after implantation could occur, correct?

A. Where are you reading that?

If you pick out this sentence in the middle of the paper, I don't know how to answer your question. You've got to tell me where you are reading it.

Q. "One small longitudinal study suggested that most of the difference between in vitro and in vivo mesh dimensions was due to surgical technique, i.e., folding and warping of the mesh during or immediately after implantation."

Did I read that correctly on Page e3?

A. Where on e3 are you reading it?
Q. Last full paragraph.
"One small longitudinal study suggested that most of the difference between in vitro and in vivo mesh dimensions was due to surgical technique, i.e. folding and warping of the mesh during or immediately after implantation."
MR. MORIARTY: And what's your question?
Q. My question is, if folding and warping of the mesh occurred during or immediately after surgery, it would not be depicted as a change in the dimensions of the mesh when the first scan is done at three months, correct?
A. I don't know.
Q. You don't know? If it occurs immediately after surgery would you be able to tell the difference if the first scan is done at three months?
A. I mean, I don't know enough about the sensitivity of that or how -- again, I just don't have a whole lot of familiarity with translabial ultrasound to say.
Q. Well, this is the one study you picked

out of all the dozens, hundred studies describing shrinkage of mesh. I'm just asking you opinions on why this was the conclusive study or whether it just supported --

A. I mean, it was one of the studies.

Q. What you --

A. All the studies -- again, there is a body of literature and you have to pick out certain studies, and so this is one of the ones that was included. I mean, there is --

Q. So of all the dozens and every single other study conclusively shows that mesh shrinks, this is the one that you picked?

MR. MORIARTY: Objection, form. Go ahead. Argumentative. You just want to argue with him all day.

A. I don't think there was a question there. This is the study I picked.

Q. What is the dimension of the Perigee that was used in this study when it was inserted? Or if you will take my word for it, it's 5 by 3.7 centimeters. Does that sound right?

A. So, it's in the materials and methods. Your Perigee was I guess an American Medical

Systems product. This isn't even an Ethicon product. Sure, I would believe this. They describe that. I guess they measured it, and it's 5 by 3.7 centimeters.

Q. Well, you chose the paper about Perigee, not me, right?

MR. MORIARTY: Objection, argumentative. What does that have to do with anything?

MS. THOMPSON: Well, he was questioning that it wasn't even an Ethicon product, and I was just bringing to his attention that he was the one that picked a non-Ethicon paper when there were other Ethicon papers he could have chosen.

MR. MORIARTY: I thought you were asking about the dimensions of the Perigee.

MS. THOMPSON: I am.

BY MS. THOMPSON:

Q. Now, if you go to the chart on Page e3 giving the dimensions, the lower mesh margin.

A. Table 1 or Table 2?

Q. Table 1. And the mesh link, those measurements are significantly different, smaller

than 5 by 3.7, correct?

A. So, the coronal mesh diameter was 3.71 and then 3.77, so that actually is I think just the same as the 3.7. Is that --

Q. Well, the lower mesh margin would be the width, correct, and the mesh length would be the length, correct?

And you get something like 1, between 1 and 1.45 for the width and you get 3.28 to 3.41 for the length, correct? I'm just reading numbers.

A. I apologize. We are going to have to go off the record for a second. I need to look at this. I haven't familiarized myself with this in a little while, and you are asking me all these --

Q. Are the numbers 1 and 3.4 less than 3.7 and 5?

A. I can't answer any questions about it. If you can give me a few minutes to read this over.

Q. So this was a paper you chose, but you are not at this time able to answer any questions about the dimensions?

A. The very detailed, specific questions you are asking about one of the 50 papers that I've cited, I want to answer your questions --

Q. Excuse me.

MR. MORIARTY: Stop cutting him off, please. Even the court reporter has told you to stop it.

MS. THOMPSON: I'm sorry.

A. I want to answer your questions accurately, and if you want to get into the minutia of this little paper, which, again, it was cited and so I'm perfectly willing to do it, but you are going to have to give me a minute to better understand it, because this is a paper that was on something that I don't typically do and while the other papers I'm much more familiar with because I do the surgeries, I don't do the ultrasounds, and you are asking me about numbers and how they were interpreted. I need a few minutes to look it over. I can do that, if you want.

Q. I don't want to spend the time because my time is so limited, but you certainly would need time to understand this paper, the one paper that you cited on shrinkage, correct?

A. I would need a lot of time, but you are asking me again how to interpret their tables and how the dimensions were being measured, and I need

a few minutes to read over their methods. I'm happy to do that.

Q. It's only a four-page paper, right?

A. You are the one who says we don't have time. I have plenty of time.

Q. Let's go ahead and look at some shrinkage information on Ethicon products. Okay?

A. Okay.

MS. THOMPSON: We will mark this as 25.

(Bales Exhibit 25 was marked for identification.)

BY MS. THOMPSON:

Q. And I'm looking specifically at the abstract 157 by the authors Letouzey and De Tayrac, among others. Are you aware that these authors are part of the TVM group in France?

A. Yeah. I think I recognize the Levaillant. I'm not perhaps pronouncing that, the Levaillant name.

Q. And this study actually used Gynemesh, correct?

A. Yes.

Q. And it was placed under the bladder in a

tension-free procedure, correct?

A. Correct.

Q. And the results of this study showed that ultrasound evaluation reconstruction has been shown to -- a typo -- has been showed a mean contraction of 30 percent, 65 percent, 85 percent at a mean followup of 3 years, 6 years and 8 years respectively, correct? Did I read that correctly?

A. Yes.

Q. 85 percent at 8 years is certainly not any clinically significant degree, as you stated in your report, is it?

A. Well, you know, it is interesting. If we read just a little further, there was no significant correlation between mesh position and clinical outcomes. So actually, it seems to indicate by their results that while it's contracted, it hasn't affected outcomes. So, I guess it's not clinically significant if you believe this one abstract.

Q. Did the mesh shrink in this abstract by Dr. Tayrac?

A. Well, according to the ultrasound measurements, you just stated the numbers,

30 percent, 65 percent, et cetera.

MS. THOMPSON: We will mark this as Exhibit 26.

(Bales Exhibit 26 was marked for identification.)

BY MS. THOMPSON:

Q. Did you look at any Ethicon documents regarding mesh shrinkage and the clinical significance?

A. Yes, I looked at some documents.

Q. Did you look at this document that I just marked as Exhibit 26 that says, "Mesh shrinkage: How to assess, how to prevent, how to manage?" by authors Velemir, Fatton and Jacquetin, also part of the TVM investigating group on Gynemesh and Prolift? Have you seen this document?

A. I may have.

Q. Go ahead and look through it, if you would like, and let me know when you are ready.

A. Well, I don't know what to be ready for, so I'm not sure if I'm ready.

Q. I want to ask you some questions, but I will direct you to the right place.

A. When you don't know what to expect, it

is hard to know if you are ready.

Q. Fair enough. And this entire document, it looks like it was a workshop, is postoperative specific complications following transvaginal mesh repair of pelvic organ prolapse, etiology, prevention and management; and the entire -- I don't know how many pages it is but it's long -- is about mesh shrinkage, correct?

A. I don't know. I didn't have time to go through every single page just now.

Q. Well, the title is "Mesh Shrinkage," so you can probably assume that the document is about mesh shrinkage, right?

MR. MORIARTY: Your question was whether every page of the thing was about mesh shrinkage, so don't get frustrated by his answer when he hasn't assessed because I'm looking at the third page and it isn't about shrinkage. So, I understand your frustration, but if your question is going to be that way...

BY MS. THOMPSON:

Q. Okay. Let's just go through several of these pages. All right. It gives a definition of

mesh shrinkage on page -- the second page, reduction of the mesh area after tissue incorporation, correct?

A. That's what it lists as the definition.

Q. And it also says it's often associated with mesh thickening and folding, correct?

A. That's the third bullet point there, yes, often associated with mesh thickening and folding.

Q. Would you disagree that mesh shrinkage is often associated with mesh thickening and folding?

A. That hasn't been my experience.

Q. So you would disagree with Ethicon that mesh shrinkage is often associated with mesh thickening and folding?

MR. MORIARTY: Objection, objection to form.

Q. You can answer.

A. It hasn't been my experience that I have seen in my own patients a lot of mesh thickening and folding, so I don't know who I'm disagreeing with, but you asked me what my opinion is, and I haven't seen that.

Q. And do you have any peer-reviewed literature that would tell you that mesh shrinkage is not associated with mesh thickening and folding?

A. I guess we will have to go through and find some literature. Again, there is lots of literature that there is mesh contraction, but specifically regarding the folding and how the folding is measured, I'm not aware of any literature telling me that or showing me that or quantifying that.

Q. I'm asking are you aware of literature that says it's not associated with thickening and folding, not that it is.

MR. MORIARTY: Objection, asked and answered.

Q. Two different questions.

A. I guess I'm not sure that there is literature specifically talking about the folding and the thickening.

Q. Okay. Would you agree that mesh shrinkage is well-documented in animal studies with a range of 15 to 65 percent?

A. Yes, there is animal studies that show that. I would agree with that statement.

Q. Would you agree that mesh shrinkage is a phenomenon experienced by abdominal surgeons?

A. When using mesh for what procedures? So use mesh for ventral hernias, for instance, or what specifically?

Q. I'm just reading. Do you agree with the statement from Drs. Velemir, Fatton and Jacquetin of the TVM group in France investigating Gynemesh and Prolift that mesh shrinkage is a phenomenon experienced by abdominal surgeons?

A. Well, I guess I don't disagree, I don't agree. I'm not sure what they are referring to there, so I don't want to just --

Q. So you can't answer that question?

A. Again, let me finish. As a blanket statement I just want to say I agree. I'm just not sure what they are referring to.

Q. And do you agree with the statement that mesh shrinkage is a phenomenon which has become a rising concern in urogynecology since the widespread use of vaginal mesh?

A. I think it's a concern for urogynecologists, urologists. Anybody who is using vaginal mesh, it would be a concern.

Q. Except it's your opinion that it has not been shown that vaginal mesh contraction is of any clinical significance, correct?

A. Right. That's a different question, right. So, we are always concerned about these complications and risks and whether or not there is any clinical significance. It's my opinion right now that I'm not sure what the clinical significance is.

Q. Well, you said you don't believe there is clinical significance, correct?

A. Correct.

Q. All right. So it hasn't been a --

A. For instance -- just let me finish. For instance, the previous exhibit indicated that there was again that mesh contracture but no difference in clinical outcome. So, that's a prime example of what I believe, so, anyway...

Q. Well, you said that contraction hasn't been conclusively established?

A. Contraction.

Q. Going to the next page, what did we learn from abdominal wall repair studies?

"Several complications associated with

the use of mesh may be due to chronic inflammatory reaction to the mesh or a loss of compliance after degradation of the material."

Do you agree or disagree with that statement by these authors, published by Ethicon?

MR. MORIARTY: Objection, form.

I'm sorry. Did you say published by Ethicon? There is nothing that says this is an Ethicon document. It's from some IUGA seminar.

MS. THOMPSON: I apologize. By the authors that were the Ethicon investigators of the Gynemesh and Prolift products.

BY THE WITNESS:

A. It would be nice to see it in the context, but basically complications -- let's read. The bullet point says several complications may -- may be due to chronic inflammatory reaction to the mesh or loss of compliance.

So, I guess I would agree with that, although it would be nice to know specifically in what context they are talking about and what -- you know, in what type of surgeries and what have you, but on balance I guess I would agree with that

statement.

BY MS. THOMPSON:

Q. And actually going to the bullet point above that, mesh repair reduces the rate of recurrence compared with traditional suture repair and works by both direct mechanical sealing, sublay, and induction of a scar plate formation.

Do you agree with the statement that mesh repair induces a scar plate formation?

A. I -- yeah, I agree with that statement 100 percent. For abdominal wall repairs, mechanical sealing, right, the synthetic, the mesh is there and also scar happens and further reinforces the repair. I agree with urethra.

Q. Is a scar plate a good thing to have in the vagina?

MR. MORIARTY: Objection. Go ahead.

A. Well, I'm not sure exactly I guess what the difference is between a scar and a scar plate, right. I guess it's kind of maybe a poor term. I think scarring is something that occurs after we do surgery. So, obviously, less scarring is better than more scarring, but again, I'm not sure what we mean by a scar plate.

Q. You are not familiar with the term "scar plate" used in mesh literature extensively?

A. I'm very familiar with the term. I'm just not sure how it differs from just a scar and what it conveys in terms of the size of the scar and the thickness of the scar, any of that. Again, it's not a very good term in terms of what it conveys. So, I say you have a scar plate. What does that mean? You have a 1 centimeter, you have a 5 centimeter scar?

Q. So you don't know what the term "scar plate" means?

A. I think I just indicated that I know exactly what a scar plate is. A scar plate is simply just a scar, and there is no absolute literature saying what the -- it's not a good term because it doesn't mean any specific size or thickness or anything.

So, I'm familiar with the term, we use the term a lot, but it doesn't necessarily indicate the size of the scar or what significance it may have clinically.

Q. So is it your opinion that "scar" and "scar plate" mean the same thing?

A. Yes.

Q. And then mesh shrinkage, and again we are talking about what did we learn from abdominal wall repair studies. "Mesh shrinkage folding and migration may result in some cases in a recurrent hernia and also pain," do you agree or disagree with that statement, that mesh shrinkage folding and migration may cause pain?

MR. MORIARTY: Objection, form.

A. I don't agree or disagree.

Q. You don't agree or disagree? You can't answer the question whether shrinkage, folding and migration can cause pain?

A. Well, I suppose if it says "may," I suppose it could. Again, I would need to know the clinical context. It's such a generic thing, mesh migration. So if the mesh moves a little bit, it's going to cause pain. If you put mesh in somebody, they can get pain. I guess I'm not sure how to answer that.

Q. So you have trouble answering the question of whether you agree with the statement by these authors that mesh shrinkage, folding, migration may cause pain?

MR. MORIARTY: Objection, form. Go ahead.

A. I have trouble not knowing specifically what they are referring to. I don't want to make a blanket statement yes.

Q. Okay. Let' go to the next page.

MR. MORIARTY: Time for a break, unless you have to get to that next page before the break.

MS. THOMPSON: No, I don't have to get to the next page.

MR. MORIARTY: I think you have an hour left.

MS. THOMPSON: I will be fine with an hour.

(Recess taken, 11:02 - 11:16 a.m.)

BY MS. THOMPSON:

Q. Dr. Bales, let's go to the -- I think it's the next page, "What is specific to vaginal surgery?" And these authors state, "Poor knowledge of the vagina in vivo response to the materials." Do you agree or disagree that there is poor knowledge of the vaginal in vivo response to the materials?

A. Oh, I think we are learning more and more. I don't know exactly what the timeframe was on this, but for sure it's newer, right, that we are putting these materials into the vagina, so I think we have an evolving knowledge. I guess that would be more correct to say.

Q. When the Prolift was on the market, Gynemesh and Prolift for transvaginal use, was there poor knowledge of the vaginal in vivo response to the materials?

A. I think there was limited knowledge.

Q. So you take exception with the word "poor" but agree that it was limited?

A. I would use the term, yeah, "limited." I wouldn't be comfortable saying "poor." It is limited.

Q. Do you agree that the vagina has an important vascularity and endogenous microflora that may have an impact on host tissue response and biomechanical properties of grafts used in pelvic reconstructive?

A. Yeah, I agree with that 100 percent.

Q. Going to the next page, "What do we observe with mesh repair in our field?" And the

statement is "Mesh shrinkage may be associated with," bullet points, "stiffness/tenderness at vaginal examination." Would you agree with that?

MR. MORIARTY: Objection, form. Go ahead.

Q. Would you agree with mesh shrinkage may be associated with stiffness and tenderness at vaginal examination?

MR. MORIARTY: Same objection.

A. I guess I would agree. May be associated, I guess I could agree with that statement.

Q. Would you agree that mesh shrinkage may be associated with discomfort, pain during intercourse?

MR. MORIARTY: Same objection.

A. I guess I would just underscore again that I don't know how easy it is to determine whether mesh shrinkage is what's causing discomfort and pain after intercourse, so that's why. So, I guess may, may be associated, sure. I guess I could on balance say that's okay.

Q. And you certainly agree that there are many papers where the authors are able to make the

connection between the shrinkage, retraction, contraction and pain; you just are not able to, correct?

MR. MORIARTY: Objection, form. Go ahead.

A. Yes, I'm not able to.

Q. Do you agree with the statement mesh shrinkage may be associated with pelvic pain?

MR. MORIARTY: Same objection.

A. I think it was the same thing we said before. There is -- when patients have pain, specifically the mesh being possibly shrinking or is shrinking, is that the cause of the pain, I guess it can be hard to say. So, that's my only concerning about making that blanket statement.

Q. Do you agree or disagree with the statement mesh shrinkage may be associated with urinary or defecatory dysfunctions?

MR. MORIARTY: Same objection.

A. I -- yeah, I guess I'm not sure if the mesh -- yeah, I guess I'm not prepared to say mesh shrinkage causes urinary or defecatory dysfunction, so no.

Q. Do you disagree or agree with the

statement mesh shrinkage may be associated with prolapse recurrence?

MR. MORIARTY: Form objection. Go ahead.

A. I would say that mesh shrinkage or mesh loosening, so yes, I would agree with that, could be associated with prolapse recurrence. I would say yes to that statement.

Q. And these authors cite three papers to support the statements that they make on this page of this presentation, correct?

A. I guess. I mean, it looks like these are slides, right? I mean, again, it seems to me that maybe this was IUGA, right. It was at a meeting and these are just copies of slides, I think, so these obviously are the papers they cite. I would have to go back through those papers are, but sure, it looks like they are giving those citations.

Q. Yeah, and my question was just the authors cite three papers.

A. Citations are definitely there.

Q. And I'm using the word "presentation" on when we are talking about this document, if that's

acceptable to you.

A. That's what it seems like it is.

Q. I actually counted approximately 25 articles cited in this presentation by these three authors, correct? Would you agree that's something in that neighborhood from your perusing the document?

A. I would believe you if you said you counted them and there is 25.

Q. I said approximately, so don't hold me to an exact number either.

Okay. The next page, "Why does mesh shrinkage happen?" The bullet points, "An unclear etiology" is the first one. The second is "Shrinkage should not be considered as a complication of the biomaterial but as a consequence of the incorporation of the mesh to a scar tissue," and the third, "Biomaterials, even polypropylene, are not inert" with a exclamation point.

Do you agree with these authors who gave these three bullet points as why does mesh shrinkage happen?

MR. MORIARTY: Objection, form.

A. Again, there is three. Mesh shrinkage, they say it's unclear, there is an unclear etiology. I agree with that.

Shrinkage should not be considered a complication of the biomaterial but more incorporation of the mesh to scar tissue, I guess I would agree with that, although I think they -- they -- they cite their first bullet point that there is an unclear etiology and then they say, well, it's because of this. So, I think it's still perhaps a little bit unclear.

And biomaterials, even polypropylene, I would not agree are not insert. They cause some response, some host response.

Q. On the next page, histological sequence after mesh incorporation, and it gives basically a pathological process by which it happens, correct?

A. They discuss, right, how a immune response occurs, there is inflammation and then some of the wound contracture; yeah, they do. That's what the slide is.

Q. And there are two articles cited on this page as well, correct?

A. Yes.

Q. It says mesh contraction essentially takes place during the first two months, correct?

A. That's what it says here.

Q. So, if this were true, the Dietz paper who looks at shrinkage or contraction beginning at three months would not provide very much information on any shrinkage or contraction that takes place in the first two months, correct?

MR. MORIARTY: Objection.

A. Well, it might still be beneficial because, remember, they knew the starting point incident, and if the contraction occurs in the first two months, it's not going to re-expand. So, if you look at it at any point after two months, you will still be able to determine that the contracture occurred, so it may still provide very valuable information.

Q. Well, you understand that the Dietz paper took two points in time; the first point was after three months and the second point was sometime after three months?

A. Some time after that, correct.

Q. So you are not going to detect any shrinkage that occurs in the first two months, are

you, doing it in that method?

MR. MORIARTY: Objection, asked and answered. Go ahead.

A. Yes.

MR. MORIARTY: He just gave you an answer to that very question.

A. In a perfect world it would be nice if you had the preoperative measurements and then sequential and serial measurement at two weeks, four weeks, six weeks, and you could really learn a little bit about that.

So, I'm not immediately familiar with these two citations, so I can't know how they decided that the mesh contraction, what data they have to support that it occurs essentially in the two first two months.

Q. Okay. And I didn't ask you about the data that they have, but if you assume that mesh contraction essentially takes place during the first two months, as stated in this presentation, then a study that has their first point after three months and compares it with another point past the three months wouldn't be able to tell you anything about the contraction that takes place in the first

two months, would it?

MR. MORIARTY: Objection, asked and answered. Go ahead.

A. That's a tremendous "if," right? But sure, if you are looking for an event and if the event happened before you are looking for it, you are not going to be able to tell.

Q. Okay, all right. Thank you.

And the patients -- the authors state, "However, some observations support the idea of a chronic inflammation which persists several years." Do you agree with that statement?

A. It's such a vague statement I'm not sure how to agree or disagree. Some observations, what observations? I don't know what they are talking about, so I don't want to agree or disagree.

Q. Let's go to the page that says "How to assess mesh shrinkage? Clinical assessment."

A. Okay. I'm on that page.

Q. And one is "Transvaginal palpation of the mesh." Do you agree that transvaginal palpation of the mesh is a method to assess mesh shrinkage?

A. It's certainly a method that's used. I

agree with that.

Q. What is VAS of a vaginal pain?

A. That stands for visual analog scale. Typically you have a scale oftentimes from 1 to 100 and you ask a patient to put in a notation, zero being no pain, 100 being I guess the most severe pain you've ever had and they mark it on a piece of paper, and that's how you measure it then, so it's graded 30, 60, 90, depending on that scale. So, that's what a VAS scale is.

Q. And do you agree that VAS of vaginal pain is a method for assessment of mesh shrinkage?

A. No. VAS is a method for assessing vaginal pain. VAS doesn't tell you anything about mesh shrinkage.

Q. I guess these authors thought it was a way of quantifying the vaginal pain associated with mesh shrinkage. Would that be your assumption?

A. Obviously they would have been talking as they presented these slides, so it's a little hard to say. It looks like they are trying to make a comparison or a correlation, but again, the VAS is completely unrelated to anything about the anatomy of the mesh. It's strictly just -- it's a

pain scale that the patient describes.

Q. But they wouldn't be talking about vaginal pain from some other source, would they, on this slide about how to assess mesh shrinkage?

A. I'm not sure what they would be doing.

Q. Really?

A. Well, again, I didn't give the presentation.

Q. Okay. And the third bullet point on how to assess mesh shrinkage is "Assessment of sexual outcome." Do you agree that that would be a method of detecting, assessing mesh shrinkage?

A. Again, I'm not sure about the correlation. I think it's very important to assess pain scales and sexual outcomes, but again, I'm not quite sure where they are going with this in terms of correlating with mesh shrinkage.

Q. And then the fourth bullet point is "Use of a specific classification."

You are aware that the ICS published a methodology for determining mesh-related complications and grading them, classifying and grading them?

A. Yes.

Q. And you are aware that the ICS classification of mesh complications does give a grading system for mesh contraction and shrinkage?

A. Yes.

Q. So do you believe that that's what they are referring to under specific classification, or what is specific classification and method to assess mesh shrinkage?

A. Correct me if I'm wrong, we would have to look that up again. It has been around for I think a couple years. There is a good paper from the Cleveland Clinic that used that scale and an experience of about 25 or 30 patients. But as I said, I'm not sure that classification scale specifically pertains to mesh shrinkage. That scale just has to do with patients' symptoms and, you know, their vaginal exam.

I'm not sure part of that scale -- I would have to pull it up -- also measures or talks about the shrinkage that may have occurred.

Q. We will pull that up if I have time at the end.

So, the next couple of pages provide methods for classification, and the first is by an

author Debodinance that grades it four ways: Mesh palpable but not sensitive, moderate shrinkage and/or little symptomatic, severe shrinkage and/or symptomatic with sensitive palpation, and then grade 4, painful mesh palpation.

Would you agree that those are all -- those would be degrees of or a way to grade mesh shrinkage on examination?

A. Well, sure. I guess that's what this grading scale is for. Again, how accurate it is, that's why, as we had discussed earlier, certain practitioners now were incorporating transvaginal and translabial ultrasound to try to have a more objective scale to utilize to try to assess what's occurred there with mesh shrinkage.

Q. And the next one is a mesh shrinkage classification by Cosson and Fatton, which I believe are also members of the Ethicon TVM group in France, correct?

MR. MORIARTY: Objection. Go ahead.

A. I don't know if they are members of any group or what have you.

Q. And then they give another classification system that's 1 through 5, with

asymptomatic being grade 1; spontaneous pain, grade 5; and then a less than 50 percent or greater than 50 percent degree of protection. Would you agree that would be another way to classify mesh shrinkage?

A. Well, there is nothing in the grading scale that talks about shrinkage, so I'm not sure how you use this scale.

Q. Well, it at least says degree of retraction, "A" or "B."

A. So where does the "A" or "B" go? Is "B" the ones that goes in 3, 4, 5 and then "A" in 1 and 2?

Q. I believe -- well, this is a method of classification regardless of how you interpret it, correct?

A. Yeah. I mean, it looks like it's mostly using pain, though. I guess I'm not sure if you told me this woman who was a Grade 3 and the other was a Grade 4, what's that going to tell us about the mesh shrinkage.

Q. But it's a method of classification, correct?

A. Right, but you asked about the mesh

shrinkage. So, I don't know how I would use -- how -- you said one is a 3 and one is a 4, one is a 3, one is a 5. If you told me that, then how does it tell us what degree of mesh shrinkage is there?

Q. Then going to the next page, which is "Our Experience," and that would mean the experience of the authors, correct, who are the TVM, Ethicon Gynemesh and Prolift investigators, correct?

A. I mean, I guess. Again, you are just showing me these pieces of paper. You know, it's not part of a scientific paper. I'm not 100 percent sure what this is, but I guess. It just says "Our Experience." Whose experience? Maybe these three guys, I guess. I don't know.

Q. Object. If there are three presenters of this and they say "our experience," would you not assume that the experience they are talking to is their own?

A. Yes, but is it the three, is it one of them? Sure.

Q. You do know that these three authors are members of the TVM group, correct?

A. You told me that, yes, and I think --

Q. And you don't know that?
A. I don't know that for a fact because I don't know that.
Q. But you wouldn't know that if I hadn't told you?
A. That's correct.
Q. Okay. And we have already discussed that Dr. Jacquetin is the patent holder on Prolift, correct?
MR. MORIARTY: Objection, form.
A. You told me that. I didn't know that. I don't have any reason to doubt.
Q. And they actually state here that it is perspective, so whoever it is, I would assume "our experience" is referring to the authors, but whatever.
The prospective control of 107 patients operated on between 2005 and 2006 with Prolift, right? I read that correctly?
A. Yeah. You read everything just fine typically.
Q. Okay. Let's go to their results. Okay?
A. Sure.
Q. The next page. And they are giving the

number of shrinked mesh and the mean shrinkage, tenderness at palpation and the mean VAS in case of tenderness, correct, is what is provided in this table?

A. That's what it looks like, correct.

Q. And their conclusion was a mean 15 to 25 percent of shrinkage was perceived in 60 to 90 percent of cases, correct?

A. Yes. That's what they are saying here.

Q. That's their results that they are reporting in this presentation, correct?

A. It looks that way.

Q. And then if we go to the next page --

A. Let me just point out, it doesn't explain what scale they used or how they assessed it per se, but those are the numbers they are citing here.

Q. Okay. And then the next page is "Clinical impact of mesh shrinkage," and it appears that they are reporting on the same series of patients. Agree?

A. I guess.

Q. And the first bullet is, "Spontaneous pelvic/perineal pain related to severe mesh

shrinkage present in three patients, 2.8 percent, with a mean VAS of 5/10."

Did I read that correctly?

A. Yes.

Q. The second bullet point is, "Tenderness/ pain at vaginal examination associated with mesh shrinkage present in 21 patient, 19.6 percent, with a mean VAS of 5 out of 10."

Did I read that correctly?

A. Yes.

Q. And of the 13 patients sexually active, eight patients did not have dyspareunia, four patients had unchanged dyspareunia and one patient, de novo dyspareunia, correct?

A. That's correct.

Q. And eight patients sexually inactive, including one because of de novo dyspareunia, correct?

A. Correct.

Q. And then the next several pages are ultrasonic evaluation of mesh shrinkage, correct?

A. Yeah. It looks like that's what they are trying to do, yep.

Q. And it looks like it's from several

different authors; you would agree, correct?

A. Why do you think it's several different authors? Is there a citation?

Q. I at least see one that's from Tunn, T-u-n-n. I see one from Velemir, V-e-l-e-m-i-r. I see one that's from Shek, S-h-e-k. I think there are actually more than one study from Velemir.

A. Okay. And there is one, Lemmery, it looks like. Okay.

Q. And these all use transvaginal introital ultrasound, correct, unlike Dr. Dietz?

A. I guess, yes.

Q. It says "How to assess? Ultrasonography," and it says "Transvaginal introital ultrasound," right?

A. That's what it says on that first page.

Q. It doesn't mention ultrasound by any other technique, does it?

A. No, not that I can see.

Q. And it says ultrasonography can give objective measurement of length, configuration and thickness, correct?

A. That's what it says.

Q. And it can give a better understanding

of recurrence and postoperative pain or dyspareunia. I'm reading that correct, right, correctly?

A. You are reading it correctly.

I guess just to make clear, just because you are reading it and I agree hat you are reading everything accurately doesn't mean I agree or disagree with any of these things, right?

Q. I understand.

A. I'm just agreeing with your ability to read it.

Q. That's right, and I may ask followup questions later, but I will ask you if you agree or disagree when that's what I want to know.

A. Terrific.

Q. Understanding that you are not an expert in ultrasound evaluation of pelvic -- of mesh in the pelvic floor, you would agree that many of these ultrasound images in this presentation show folded, wrinkled or bunched mesh, would you not?

MR. MORIARTY: Objection.

A. Why do you think that? Based on what?

Q. Okay. Let's go to the first page, anterior mesh. Is the mesh in that picture lying

flat?

A. Well, as I said, I don't do these ultrasounds. If this line represents the mesh, that line between the bladder, the translucent bladder image and then the probe, you know, it's perfectly straight. I don't know. I mean, there is obviously contours in the vaginal wall. I'm not sure I see a fold there, if that's exactly -- if that's what the mesh is there, that white line.

Q. Is it lying flat?

A. Well, it may be lying --

MR. MORIARTY: Objection. He just answered the same question.

MS. THOMPSON: He didn't.

MR. MORIARTY: Yeah, he did.

MS. THOMPSON: All right.

A. If it's a bumpy surface, it may be lying perfectly flat on a bumpy surface.

Q. Let's go to the total monobloc mesh, and look in the picture upper right-hand side. Is that piece of mesh lying flat?

MR. MORIARTY: Objection. Just let the record reflect someone has drawn lines over the ultrasound image in these PowerPoint

slides.

BY MS. THOMPSON:

Q. Are you not able to interpret these ultrasounds? If so, we will just move on.

A. I'm happy to try, but I think it's wrong to assume that like the one that shows that "U," right, kind of in a "U" configuration, that might be a sling, and that's exactly what you expect it to look like, it looks like a "U," and it's lying perfectly flat because the "U" represents the proximal urethra, and that's exactly what it should look like.

So, right, I don't expect it to be a straight line. The vagina is not filled with straight lines. The vagina has, you know, curves and folds, and obviously the slings will always be -- you know, they should look like that, it should look like a "U."

So, I apologize I'm not more knowledgeable about this, but I can't answer whether it's flat or not. That might be perfect.

Q. On that page that says total monobloc mesh, you are saying that the image on the right-hand side could be a sling?

A. Yes. I don't know.

Q. And then the page that is the link of the Sonomorphological Evaluation of Polypropylene Implants by Tunn, is the mesh on the left-hand side of that lying flat?

MR. MORIARTY: I'm sorry. Where are you?

THE WITNESS: Next one.

MR. MORIARTY: Okay. Thank you.

A. So, there is two on this page. There is a left-sided one and a right-sided one. This one isn't as clear to me. I guess I don't know. I don't want to comment.

Q. Okay. And the results from Dr. Tunn's study state that the decrease of the length size of 60 percent, states that there is a decrease of the length size of 60 percent for the anterior mesh and of 65 percent for the posterior mesh.

Is that a significant amount of shrinkage in your opinion?

MR. MORIARTY: Objection. Go ahead.

A. I guess I would only say I would correlate that with -- with the anatomic exam, and so I don't know whether it's significant or not. I

don't think I need to see it correlated with the objective anatomic exam, vaginal exam and also patient symptoms.

Q. I'm not asking about exam and symptoms. I'm asking about is Dr. Tunn's findings that the mesh shrinks, and we have defined that as decrease in length size, 60 percent in the anterior and 65 percent of the posterior mesh. Is that a significant amount of shrinkage?

MR. MORIARTY: Objection, asked and answered.

A. Well, again, the mesh is only there to help the cystocele or the rectocele. So, if that shrinkage isn't causing any problems, then it's not significant, and I just don't know if -- again, there is no correlation with the anatomy or the patient symptoms and such, so I'm not sure how to interpret it. It's just a number.

Q. And he also found that the mesh supported 40 percent of the length of the anterior vaginal wall and 50 percent of the length for the posterior mesh. Is that significant?

A. Same response to the previous question. I don't know.

Q. On the following page, the paper by Dr. Shek, who looked at 46 patients with transobturator anterior mesh and concluded that patients with good clinical results had mesh well spread out, minimal folding and both effective anchoring arms, would you agree that that's what would occur in patients with good clinical results?

A. Well, it says "patient." It's not plural. It says "patient," so a patient with good clinical results, and I guess a good clinical result is desirable.

It's nice to see that this one patient with a good clinical result, it looks like the mesh is where he expects it to be, there is minimal folding and the anchoring arms seem to be effective. But as I said, I just don't know if that means if it's -- if the reason for the clinical results is because it looks so good on ultrasound.

Q. So you think that only one of the 46 patients he looked at had the good clinical result?

MR. MORIARTY: Objection.

A. No. I didn't say that.

Q. Well, you said it referred to one

patient.

MR. MORIARTY: Well, it does. It's singular right on the page you are reading from.

MS. THOMPSON: Okay. Well, we will just go with that then. We will assume one out of 46 patients had the good clinical result.

MR. MORIARTY: Objection, form and otherwise. You can't assume that. You just asked him about what's printed on this page. You haven't given him the study.

MS. THOMPSON: I suspect that's a typo, but if he believes that refers to one patient, it is on the record.

BY MS. THOMPSON:

Q. Going to the next page, Shek study, in that one a patient with recurrent cystocele had dislodgment of the superior arm and voiding dysfunction. Would you agree that dislodgment of a arm of Perigee could cause recurrence and voiding dysfunction?

MR. MORIARTY: Objection. Go ahead.

A. I don't think the -- I would disagree.

I don't think the arm causes it. I think the recurrent cystocele can cause voiding dysfunction and whether the recurrent cystocele is because of the dislodgment of one of the arms, I guess I'm not sure.

Q. Velemir on the next page in this paper states that recurrences are associated with severe mesh retraction. Would you agree that recurrences are associated with severe mesh retraction?

A. I'm sorry, counsel. Which page? This next one, Velemir?

Q. The results at the top of the page, Velemir.

A. I'm sorry.

Q. "Recurrences after transvaginal mesh repair are associated with severe mesh retraction and loss of mesh support on the distal part of the vaginal walls."

Would you agree that recurrences are associated with severe mesh retraction?

A. I guess they may be associated with some mesh retraction, but I think the more important thing is the second part of that sentence, loss of mesh support. So, I think it's the support, not so

much whether the mesh is contracted a little. I think it is the actual support that is more essential to the recurrence.

Q. Do you use sutures to fix -- when you used Prolift, did you use sutures to fix the device?

A. On a case-by-case basis. There wasn't -- sometimes we would supplement things by helping it sort of spread out if the anatomy necessitated it, so there wasn't a always suture use or always no suture use.

Q. I'm going to skip ahead to the "Reduce mesh exposition 10 rules."

A. How far along are we?

Q. I don't know. Past all the ultrasounds.

A. Okay. "How to prevent expert opinion," is that it?

Q. No, the next one, "Reduce mesh exposition."

A. Got it.

Q. What is mesh exposition?

A. Extrusion, exposure.

Q. Do you agree that experienced surgeons have less, a lower exposure rate than inexperienced

surgeons?

MR. MORIARTY: Objection, form.

A. I would like to think so. Obviously you need to get some studies of inexperienced surgeons and correlate that with the experienced surgeons, but I think in general probably experienced surgeons tend to get better outcomes.

Q. And you would agree that most of the peer-reviewed literature is published by experienced surgeons, correct?

A. Not always, but a lot of it is, sure.

Q. And because of that, you oftentimes don't see results in the peer-reviewed literature of less experienced community surgeons, correct?

A. I think it's safe to say that all the results that occur of any procedure between experienced or inexperienced surgeons, not everything makes its way into the -- into the literature.

Q. Let's talk about Prolift in particular. Are any of the Prolift studies published by inexperienced community surgeons?

MR. MORIARTY: Objection.

MS. THOMPSON: It's a good question,

actually.

MR. MORIARTY: It's a great question but not for this setting, so I will object to it, form and otherwise, but you can answer it.

A. Well, you know, I don't -- I will just answer by saying I don't know what absolute number you go from inexperienced to experienced, and we can argue about that all day, right, and so you would have to look at it. But there is a lot of studies, and really, without looking at every single one of them it would be hard to say.

I think your point earlier, generally more experienced surgeons have more results to write about and generally write up their experiences. So, less experience, whether you are in an academic institution or in private practice, probably write up their experience less just because they have smaller numbers; and when we try to publish papers, a greater experience allows you to get the paper published.

Q. Let's narrow it down a little bit. Are any of the Prolift RCTs published by community physicians?

A. So, for instance, Peter Sand here in

Chicago, he works at Evanston Hospital. He is in private practice, so he is considered a community doctor even though he has got a fellowship. So, it depends on how you define these things. Again, I don't know if it is a good terminology to use community or --

Q. Are any of the Prolift RCTs published by community surgeons?

MR. MORIARTY: Objection, asked and answered.

Q. He talked about Peter Sand. Peter Sand hasn't published an RCT on Prolift, has he?

A. Well, he published on a lot of experiences with mesh-type procedures.

Q. Has he published an RCT on Prolift? That was the question.

A. I don't think so. He has published on Boston Scientific's product.

Q. I will ask again. Have any of the Prolift RCTs been published by community physicians?

A. I'm not sure.

Q. And if that's what you are relying on for your data, you would not be able to determine

data that would be coming from community surgeons, correct?

A. No. Why is that?

MR. MORIARTY: What's what you are relying on data?

Q. If you are relying on Prolift RCTs for data, you would not be able to determine what the data would be if reported by community physicians, correct?

A. Well, we just said we are not sure whether some of the community physicians have published [overlapping and indistinguishable speaking].

Q. Assuming that -- that no RCTs have been published on Prolift by community physicians, you wouldn't be able to tell what the community physician experience would be compared to the physicians who are publishing the RCTs, correct?

A. Well, no. You wouldn't have RCTs but we -- you know, we get community experiences all the time. We see their patients because they get sent into academic centers. We go out to --

Q. With complications, right?

A. Sometimes there are complications. We

go out to, you know, dinner and we have, you know, meetings and we have a Chicago Urologic Society. We talk about this all the time.

So, I think at least in Chicagoland the community urologists have a lot of input into sort of our -- you know, what we discuss and stuff, so we have some sense about that. But I guess, no, if they are not -- the RCTs, if they are not producing any RCTs, then obviously we are not going to get that information on RCTs.

Q. Do you agree that there is a knowledge gap between community mesh users and academic physicians who are taking care of mesh complications, as is well published in the medical literature?

A. That the knowledge gap is well published?

Q. A knowledge gap.

A. You say there is a knowledge gap that's well published?

Q. Yes. Do you believe there is a knowledge gap as is published in the literature?

A. Well, I think that's an awfully broad statement to make. I think some community guys,

there may be a knowledge gap, but, you know, I don't know if it's universal.

Q. I didn't ask if it's universal. Is there a gap?

A. Well, again, yes. So, no; there is a gap in some places, there is not a gap in other places. So, you know, again, you have to say where. I mean, there is some excellent -- some doctors I trained who have had a wealth of experience working with me and work at Christ Hospital, you know, seven miles down the road; and so he is a community urologist but he is excellent, has a wealth of experience. So, I'm not sure. There wouldn't be a gap between he and I.

Q. Moving to the page -- well, "Use large mesh taking into consideration a global mesh shrinkage of 40 percent." Do you see that page?

MR. MORIARTY: Where are you?

MS. THOMPSON: Two pages from where we were.

BY MS. THOMPSON:

Q. Well, let's go to the next page. So, the next page is how to prevent mesh shrinkage, and that would be modulate the mesh characteristics,

and it includes mesh size, pore size, quantity of materials, other including textile structure, weave configuration and fiber diameters.

A. What is this referring to? It says how to prevent. What are they preventing here? What is it?

Q. Well, don't you think they are talking about mesh shrinkage since it's how to prevent?

A. Well, the previous slide was on mesh exposure, so why do you think it --

Q. Okay. Well, let's say either one. Let's say mesh exposure or shrinkage, how to prevent, modulate the mesh characteristics. Do you believe that mesh characteristics have something to do with mesh exposure or mesh shrinkage?

A. I think the quality of the mesh has a lot to do with outcomes.

Q. The next page, "Use large mesh taking into consideration a global mesh shrinkage of 40 percent." Is 40 percent mesh shrinkage that you need to take into consideration significant?

A. Again, we talked a little bit about that before. No, I don't know where that 40 percent number comes from.

Q. We are going through this paper with 25 citations, all of which are discussing shrinkage and the clinical implications; and the only paper you provided in your expert report was one from Dietz, the only paper in the literature that questions the phenomenon of mesh shrinkage. Why is that? I can't understand it.

MR. MORIARTY: Objection, form. Go ahead.

A. Again, counselor, you know, if I had -- if I probably had more time I probably would have included more resources and references, but, you know, we picked out some of the papers we did, and certainly you are allowed to be critical of some of them. But you know, it's a published paper in the peer-reviewed literature, and obviously it's been peer reviewed. You know, we selected it, so I don't --

Q. It was one paper that supported your opinion, correct?

MR. MORIARTY: Objection. Go ahead.

A. Yes.

Q. And who is "we"?

A. Well, again, it's my work, but as you

know, it was, you know, put together and looked at by some of the other attorneys and such. But again, it's my work, it's my report.

Q. And then the next page, "Influence of mesh porosity on tissue reaction and mesh shrinkage." Would you agree that mesh porosity has an effect on tissue reaction and mesh shrinkage?

A. Yes.

Q. And there are three publications supporting that, correct?

A. I'm sure there is more, but there are three cited here in this, on this slide.

Q. And the next page, "Influence of mesh quantity." Do you agree that lightweight meshes may have greater biocompatibility and may reduce patient complaints?

A. Yes, I would agree with that.

Q. And less material equals less host tissue response; do you agree with that?

A. Correct.

Q. And there are four citations for those statements, correct?

A. Yeah, it looks like maybe three on that one. Is there three?

Q. Three. Sorry. I meant three.
A. That's okay, counsel. We have been going for three hours. That's no problem.
Q. We are on the next page. We'll skip how to prevent the future.
"How to manage dyspareunia, shrinkage and bands," and it gives the various methods of treating dyspareunia, shrinkage and bands.
Did you see anything in the information that Ethicon provided to physicians that advised physicians on management of the mesh complications with their products?
A. Anything like a -- what specifically?
Q. Like if you talked anything about removing mesh or managing mesh complications.
A. I don't think so.
Q. Going to "Mesh excision, Our experience," and I'm going to assume that's the experience of the authors of this presentation, but whichever, they report 121 surgical procedures performed by vaginal mesh complications in our unit from 1997 to 2006. That's what it says, right?
A. That's what it says.
Q. And most cases were referred.

Is it your experience that most cases of mesh complications are referred rather than treated by the original implanting surgeon?

A. You know, I'm not 100 percent sure the denominator, but I can tell you my personal experience is that the vast number, the much higher percentage of the mesh complications I have taken care of have been referred in. They are not my own patients.

Q. And you are aware that the medical literature also supports that most referrals into tertiary academic centers are coming from someone other than the original implanting surgeon, correct?

A. Well, sure. It wouldn't be a referral then if it was your own patient.

Q. No. I'm saying the referrals are not coming from the original implanting surgeon; they are coming from someone other than the original implanting surgeon.

MR. MORIARTY: Objection. You mean like lawyers, or what are you talking about? Doctors?

MS. THOMPSON: Doctors other than the

original implanting surgeon.

A. I didn't know that. Is there literature to support that? I didn't know that.

Q. Yes, there is.

A. Okay.

Q. And so in their experience here, of the 121 surgical procedures to remove -- and we don't have a denominator at least on this page that we are looking at, correct?

A. Sure.

Q. And probably not in the procedure since most of them were referred.

Pain is the reason for the surgical procedures in 19.8 percent, at least in this experience, correct?

A. Yes. That's what it says here.

Q. And removing mesh can be a morbid procedure, correct?

A. It can be.

Q. And it's not something that you would take lightly, remove a patient's mesh for lots of reasons, correct?

A. Well, it depends on the patient and the amount of mesh, but in general, sure, it's a

complication. And again, I like to think that any procedure we do we take seriously, but for sure.

Q. Because it could create a recurrence of the condition, correct?

A. Absolutely.

Q. It could not alleviate the symptoms that the patient is presenting with, correct?

A. Depending on the symptoms it may not.

Q. And at least in some procedures removing the mesh requires extensive dissection and sometimes damage to adjacent organs, correct?

A. Well, I guess there was a risk of damage to the adjacent organs. I like to think that in the academic centers where people have experience we are generally not damaging adjacent organs, but...

Q. What about in nonacademic centers where the physicians don't have the experience that you do?

A. I'm not sure what's going on in those places.

Q. And you have never seen anything published by community doctors that are taking care of mesh complications or removing mesh either,

correct?

A. Yes, I can't say I have, but there is a lot of literature out there. There may be some of those papers were community doctors, possibly.

Q. Going to the "Concerns raised by mesh removal."

A. Yep.

Q. Let's go to the second bullet point. "Severe mesh retraction often requires a complete removal of the mesh to relieve symptoms and avoid multiple procedures." Would you agree with that?

A. It may. It's a very broad statement. I'm not sure you can say that it always requires complete removal of the mesh.

Q. Well, the statement was often requires, so not may and not always. Would you agree that severe mesh retraction often requires a complete removal of the mesh?

A. I don't know. What does often mean? What percentage of the time?

Q. So you can't answer that question, whether you agree or disagree with that statement?

A. Well, no. I agree that it may require a complete removal. I just didn't want to quantitate

the frequency.

Q. My question wasn't whether it may. My question is do you agree with the statement severe mesh retraction often requires a complete removal of the mesh to relieve symptoms and avoid multiple procedures?

A. Wait. So as I said, if it said "may" and not "often" I would agree with it. I don't know what the difference is between "may" and "often."

Q. So you can't answer the question if you use the word "often" because you don't know what "often" means; is that what you are saying?

A. Correct.

Q. And that's fine. I just want to make sure we have the correct opinion.

A. I agree. I'm just trying to be accurate with my statements.

Q. Okay. Three, "If the arms of the mesh are involved in the symptoms, the dissection has to be carried out quite laterally so the arms can be transected as deep as possible."

Do you agree with that statement?

A. I agree with that statement.

Q. The next one, "Complete resection may induce prolapse recurrence and vaginal distortion/ shortening which can be taken into consideration before and during the surgery." Do you agree with that statement?

A. I agree with that statement.

Q. Okay. Let's go to the conclusion page, the next page. "Conclusion. Mesh shrinkage is real." Does that contradict your opinions given in your expert report?

MR. MORIARTY: Objection.

A. I think all along I have told you that I believe mesh shrinkage can occur. At issue I think between you and I was how clinically relevant it is.

Q. Let's read your exact statement, which is "There is no medical literature conclusively establishing that mesh contracts with vaginal use to clinically significant degrees." Is that still your opinion?

A. Yes.

Q. Despite these 25 papers cited in this describing significant mesh contraction and the clinical implications, you still will go with your

opinion based on Dr. Dietz's article only there is no medical literature conclusively establishing that mesh contracts with vaginal use to clinically significant degrees?

MR. MORIARTY: Objection, form. Go ahead.

Q. Are you maintaining this opinion?

A. I'm maintaining that opinion.

Q. And mesh shrinkage occurs during the scarring and remodeling process; do you agree with that?

A. Yes.

Q. May result in an unpredictable way in severe complications, including dyspareunia, pain and recurrence; I guess you disagree with that statement?

MR. MORIARTY: Objection, form. Go ahead.

A. Well, yes, I guess I would disagree with that. I guess it's unpredictable. I would agree that everything is unpredictable here with mesh shrinkage and these complications.

Q. Do you agree that mesh shrinkage may require mesh removal?

A. In and of itself, a small degree of shrinkage, I don't know why then it would necessitate mesh removal. I think you would have to have other symptoms to require mesh removal: Recurrence of the prolapse, pain, infection, exposure, et cetera.

Q. I'm just asking whether you agree with the statement mesh shrinkage may require mesh removal. Do you disagree or agree with that statement?

A. I disagree with that. Why would it?

Q. Mesh shrinkage must be taken into consideration during patient counseling before surgery; do you agree or disagree with that statement?

A. I think as opposed to or as it relates to outcomes, I think patient counseling should include comments about the mesh, the implications of the mesh and what may occur with the mesh after the fact.

Q. I assume you would not counsel your patients on mesh shrinkage since you don't believe that there is any literature that establishes that it contracts with vaginal use to clinically

significant degrees, correct?

A. That's correct. I specifically don't talk about shrinkage as one of my concerns and side effects and complications.

MR. MORIARTY: You have seven or eight minutes left. I'm on analog.

MS. THOMPSON: Okay. I trust you will let me go a few minutes beyond that.

MR. MORIARTY: Don't necessarily assume that.

MS. THOMPSON: Considering we have three products and I am entitled to three plus two, plus two and I only agreed to a limited time for the Doctor.

MR. MORIARTY: I negotiated a time with Fidelma because there was a disagreement over how much time we got. Does that necessarily mean I have to give you a bunch more time?

MS. THOMPSON: So that's seven minutes on the record that I have left? You didn't count right?

MR. MORIARTY: I subtracted breaks. I took a break at 90 minutes, 90 minutes, and we

are counting down to 60 minutes.

MS. THOMPSON: I will do my best to finish in seven minutes.

MR. MORIARTY: I will give you an extra minute or two if you are right in the middle of something, but...

MS. THOMPSON: Wow. That's hard core.

MR. MORIARTY: Well, I have been held to the same time limits in every deposition.

MS. THOMPSON: I have certainly given my defense counsel some latitude, particularly when there is this much to cover in the three hours or whatever it is, so, but I will try -- we are wasting time, so can we take off --

MR. MORIARTY: We have six more hours after you are done.

MS. THOMPSON: I understand.

And if we can subtract that couple minutes for the discussion, that would be nice. I actually just have a few more questions.

BY MS. THOMPSON:

Q. What does mesh degradation mean to you?

A. What does it mean to me?

Q. Um-hmm.

A. Well, that the mesh may -- I guess the term "degrade" just means it may sort of fracture and fragment and come apart a little bit.

Q. And is it your opinion that polypropylene mesh in the Prolift and Gynemesh products does not degrade?

A. My opinion would be that it does not degrade to any clinically relevant degree.

Q. And if you were shown Ethicon documents that contradict that, would that change your opinion?

MR. MORIARTY: Objection, form. Go ahead.

A. No.

Q. And what is the basis for your opinion that polypropylene mesh as used in the Ethicon products does not degrade?

MR. MORIARTY: Objection, form. Go ahead.

A. So, primarily my hundreds of cases that I have done and the other probably 150 cases of going back in mesh-related complication cases and such, and it's just never been my experience that

degradation has -- is a reason for any -- any -- is a cause of any clinical significance.

Q. Is there any peer-reviewed literature that would tell you that polypropylene mesh in Ethicon products does not degrade?

A. I don't think there is good literature supporting that it does or does not that has any clinical significance.

Q. What have you done in your clinical practice to test for degradation?

A. Well, obviously we go back sometimes when we go back and reoperate and so you find the mesh, and it's never been my experience that the mesh is gone or has fragmented or is no longer in place. Again, it always scars in pretty well and it always seems like the mesh is pretty intact, so that's why it --

Q. Does the fact that it's not gone mean it hasn't degraded?

A. Well, if it degrades, you would expect it, right, to fragment and be apart and not still be a continuous body and have the same degree of cohesiveness.

Q. Have you ever looked at degradation

histologically in mesh samples?

A. I have been shown pictures and stuff, and there has been some literature on that a little bit. But as I said, I don't disagree that perhaps some degradation may occur. The thing is whether it occurs to the extent that it is of any clinical relevance. Histologically or under the microscope, you know, you might be able to see a few fragments or what have you, but I don't think that equates to any appreciable concern clinically and surgically.

Q. What would be the latency period between placement of mesh and the development of a malignancy if it were to occur?

A. The latency period?

Q. Yes. Do you know what latency period means?

A. I do.

Q. Okay. What would be the latency period as published?

A. Well, I mean, obviously a latency period could be anything, right? You can have a mesh -- you know, we have been putting these things in since, what, 2005, 2006 we said. So, you know, maybe there is latency period of 40 or 50 years.

I just don't know, but I don't think there is any literature to support that there is any concerns about a latency period and the development of carcinogenesis.

Q. If the latency period was 30 years, we have not been using transvaginal mesh long enough to be able to appreciate whether there is a malignancy potential or not, correct?

A. That's absolutely correct.

Q. Going to your opinions regarding your opinions the IFU, it's your opinion that the IFU is not intended to serve as a comprehensive guide, correct?

A. The IFU is not a comprehensive guide.

Q. And is it also your opinion that all of the -- well, I will just read it. Isn't it your opinion that the Prolift IFU adequately warned of all risks and potential complications associated with the Prolift?

A. I think on balance the IFU was thorough.

Q. So it did warn of all risks and potential complications associated with the Prolift?

A. Well, one risk of doing vaginal surgery

or any surgery is a patient can have a heart attack or a patient could die from the anesthetic. So, the IFU didn't discuss that, so no, the IFU wasn't 100 percent comprehensive because there is always complications that can occur that aren't cited.

Q. Did the IFU discuss chronic pain?

A. We will have to pull out the IFU so I can read it. There has been several variations and several versions of the IFU, right? So it changed a little bit.

MS. THOMPSON: Mark that.

(Bales Exhibit 27 was marked for identification.)

BY MS. THOMPSON:

Q. Is this a Prolift IFU that I just handed you and marked as Exhibit 27? Does it contain anything regarding chronic pain?

A. Yes. It discusses inflammation and, you know, scarring.

Q. Is inflammation and scarring the same as pain?

A. Well, it causes pain. It doesn't use the terminology "pain."

Q. Well, it does use the terminology

"transient leg pain may occur and can usually be managed with mild analgesics," but my question is does it say anything about chronic pain?

MR. MORIARTY: Objection, form.

BY MS. THOMPSON:

Q. I don't have very much time. If you could try as best you can to answer.

A. Well, there is ten bullet points, so I'm just -- so no, I don't think so.

Q. Or else I can go off the record each time you are thinking.

A. I don't think so.

Q. Okay.

A. I guess not.

Q. Is there anything that discusses a need for multiple corrective surgeries or any corrective surgery?

A. No.

Q. Is there anything that mentions that the complications may be permanent?

A. It doesn't say anything about permanent complications.

Q. What's the rate of exposure with Prolift?

A. Again, there is various rates, and it depends whether there was an associated hysterectomy, so it's not at simple as just saying Prolift across the board.

I think there is risk factors that can make a higher incidence occur. So, in general it can be anywhere from, you know, 1 to 15 to 20 percent, but as I said, there is multiple factors: Atrophic changes in the vagina, history of radiation. So, it's hard to just come up with just one number.

Q. You discuss in your report several patient conditions that increase risk, including smoking, poorly controlled diabetes, early return to exercise, lifting or vaginal sexual activity -- I'm on Page 7 and 8 -- and noncompliance with estrogen supplementation, and then also younger age, higher parity and concomitant hysterectomy.

Is there anything in the IFU about those conditions being risk factors for Prolift complications?

A. I don't think it discusses a whole lot about potential risk factors.

Q. Do you believe -- I'm going to hand you

the Gynemesh.

MR. MORIARTY: So we are already past the time.

MS. THOMPSON: I would like to have five more minutes. I have one more exhibit after this.

MR. MORIARTY: Five minutes less for Jake and Steve.

MR. PLATTENBERGER: We will give up five minutes, won't you, Steve?

MS. THOMPSON: I'm going to be much more hard core with my defense counsel.

(Bales Exhibit 28 was marked for identification.)

BY MS. THOMPSON:

Q. I will represent for the sake of time that this is the 2015 Gynemesh IFU, and you know that in this IFU that transvaginal use of Gynemesh is not included in this IFU, correct?

A. Yes, okay.

Q. And you will agree with me also that there is a much longer list of adverse reactions in the 2015 Gynemesh IFU than are in the Prolift, correct?

A. Yeah, there is a lot more bullet points.
Q. Dr. Bales, do you believe that mesh complications are overexaggerated or exaggerated?
MR. MORIARTY: Objection, form. Go ahead.
A. I don't know if I can say one way or the other.
Q. You can't say one way or the other whether mesh complications are exaggerated?
A. Well, so let me answer that as accurately as I can. I think there are some patients who overexaggerate their complications, but, you know, complications with mesh surgeries and any surgery, there is complications that occur, and so I don't know if we can say exaggerated or overexaggerated. So, as I said, it depends on a case-by-case, patient-to-patient basis.
For sure there are patients who I see commonly who have heard about the litigation and certainly overestimate the risk of having had the mesh. I guess that's as accurate as I could be.
MS. THOMPSON: If we could go ahead and mark that as 29.
(Bales Exhibit 29 was marked for

identification.)

BY MS. THOMPSON:

Q. Do you remember seeing this in Urology Times Urology titled "FDA warning on mesh held little surprise for urologists"?

A. Yeah.

Q. And do you see that you are one of the several urologists quoted in this what we sometimes call throw-away journal, correct?

A. You are disparaging me now. Come on.

MR. MORIARTY: No. She is disparaging the journal.

Q. Under "Concerns exaggerated?" it says, "Although he knows there can be complications, Gregory Bales, M.D..."

That's you, right?

A. That's me.

Q. And that's your picture, right?

"...suggests that some of the concerns may be exaggerated for external reasons."

Did I read that correctly?

A. Yes.

Q. And is that your opinion still to this day? I'm not sure when this was published. 2012.

A. Yeah. I think I just indicated a few moments ago that some of the patients definitely exaggerate their complications, so yes.

Q. And the quote, "At least here in Chicagoland, we have a lot of radio and television ads by attorneys, so it's on the patients' minds. I try to be proactive and have a discussion before surgery. We don't have an inordinate number of complications with mesh, and I believe it gives some patients a better long-term outcome."

Was that a quote that came from you? You weren't misquoted on that?

A. I don't think so.

Q. And a little further down you say, "Patients with significant atrophic changes won't do us well and those patients at higher risk for erosion."

You would agree with me that all menopausal women have some degree of atrophic changes unless they are on estrogen replacement, correct, or local estrogen therapy?

A. Yes, postmenopausal to varying degrees.

Q. And so that you really can't use a mesh device and count on a woman not having atrophic

changes, correct, if she lives long enough to go into menopause?

A. Correct, and again, atrophic changes vary from person to person considerably; and as you just acknowledged, we can supplement their vaginal tissue with hormonal cream and stuff to rid the patient of those atrophic changes.

Q. Is there anything in the Ethicon Gynemesh Prolift -- let met start over.

Is there anything in the Prolift IFU that states that patients with significant atrophic changes won't do as well?

A. I don't believe so.

MS. THOMPSON: That's all I have.

EXAMINATION

BY MR. MORIARTY:

Q. Okay. Doctor, I want to hand you Exhibits 5 and 6. Do you believe that you were paid those amounts in those years?

A. No, I don't remember being paid this amount in these years.

Q. Do you know whether you signed consulting contracts with Ethicon that had those numbers as a maximum amount that could be paid in

those years?

A. I remember signing contracts and I don't remember the amounts, but that certainly could be.

Q. Is there any Level 1 evidence that Prolift surgery results in more pain than native tissue repairs?

A. No.

Q. Typically do articles published in the literature just report pain as an endpoint of the study?

A. Do they report that?

Q. Pain as the endpoint of the study, as the main outcome of the study.

A. Not typically.

Q. Prior to the use of mesh for -- transvaginal mesh for pelvic organ prolapse in the early 2000s, was there literature regarding anterior colporrhaphy, posterior colporrhaphy, abdominal sacrocolpopexy and other surgeries which report as part of their studies pain as a complication?

A. Yes. We talked about that earlier.

Q. Is abdominal sacrocolpopexy primarily a surgery for apical prolapse?

A. Yes.
Q. Can you take a look at Exhibit 11, please.
MR. MORIARTY: Well, you know what? Do you mind if I use this one so he doesn't have to dig for it?
MS. THOMPSON: That's fine.
BY MR. MORIARTY:
Q. This is Exhibit 11 that Margaret asked you about, the Oversand study. Do you remember those questions?
A. Yes.
Q. And this is about long-term followup after native tissue repairs only; is that correct?
A. Okay.
Q. In the charts that report the results from their surgeries, do they have columns for complications like de novo urinary incontinence?
A. Yes.
Q. Do they have columns for urinary retention?
A. Yes.
Q. Do they have columns for dyspareunia?
A. Yes.

Q. In the dyspareunia column, are the rates across this chart 8.3, 10.7 and 9.1 percent?

A. Yes.

Q. In this other chart on the following page, Table 3, do they report de novo incontinence and dyspareunia here?

A. Yes.

Q. Are the dyspareunia rates in Table 3 similar to the ones in Table 2?

A. Yes.

Q. Are the dyspareunia rates reported in this article similar to the dyspareunia rates reported in other articles about native tissue repair and in articles about the Prolift?

A. Yes.

Q. Just because a surgeon may have concerns about a procedure or a device, does that mean that the risks of the surgery or the device outweigh the benefits?

A. No.

Q. Does it mean just because a surgeon may have concerns about something mean that the surgery or the device is unreasonably dangerous?

A. No, not at all.

Q. Margaret asked you some questions about Exhibit 23.

MR. MORIARTY: You are not offended if I use your first name, are you?

MS. THOMPSON: No, I'm not. I was going to say something cute, but I couldn't think of it.

BY MR. MORIARTY:

Q. Do you remember some questions about this vaginal mesh contraction article?

A. Yes.

Q. How many patients are in the study? There are 17.

A. Okay.

Q. And is there anything in this paper that describes in any scientific way the methodology they used to attribute the clinical complaints of pain or dyspareunia to mesh contraction?

A. No, it doesn't look like that was resulted.

Q. Okay. Thank you. I just want to ask you a couple questions about Exhibit 26. Do you remember this PowerPoint that we went through extensively? I want you to go to this page that

you weren't asked about called "The frequence of mesh shrinkage."

A. How far in is that?

Q. It is about four pages in, five pages in. Let's use this.

A. I got it.

Q. Does it say on the slide that the frequence is unknown?

A. The first bullet point says unknown.

Q. Is there then a question in the second bullet point about the clinical relevance of mesh shrinkage?

A. It says, reading bullet point, "Clinical relevance of mesh shrinkage?" It says, "Always a certain degree of mesh shrinkage, asymptomatic in most cases. "

Q. Is that consistent with your experience, that mesh shrinkage if it exists is asymptomatic in the majority of cases?

A. That's been my experience.

Q. There is another page further back in this. Let me find it. I think I dog-eared the page. It is called "How to manage? Dyspareunia, shrinkage and bands." Do you remember being asked

about this page?

A. Yes.

Q. Does one of the bullet points say, "Mesh excision improves patient's symptoms in most cases"?

A. That's what it says.

Q. Is that consistent with your experience?

A. Yes.

Q. When you gave your opinions to a reasonable degree of medical probability, is your understanding of that term that that has to do with likelihood and probabilities and more likely than not?

A. Yes, that's my understanding.

Q. Is "may" a term that in your understanding is consistent with probability and more likely than not?

A. In the context of what statement?

Q. In this context is "may" likelihood or is "may" speculation?

MS. THOMPSON: I object to the form.

A. Well, I think it may depend on what specifically I was saying, I guess, so I'm not sure I can answer that 100 percent.

Q. But would you agree with me that if you are saying something may happen that it's possible it could happen?

MS. THOMPSON: Object, leading.

A. My terminology, "may" would be consistent with "possible," not yes.

Q. Not probable?

A. Not probable. "May" would be a low likelihood, possible.

MR. MORIARTY: That's all I have.

MS. THOMPSON: I have a couple of followup questions.

MR. MORIARTY: Wait. Is there redirect when you have already used all your time?

MS. THOMPSON: I think Kersey would allow me to address a couple of points you make, and they can hopefully be very short questions.

FURTHER EXAMINATION

BY MS. THOMPSON:

Q. You are aware that there is Level 1 evidence showing that mesh repairs have a higher incidence of de novo stress urinary incontinence,

correct?

A. Depending on the study. Once again, there is a broad --

Q. Are you familiar with the Ek study?

A. Yeah. Which one?

MS. THOMPSON: We can go ahead and mark this as an exhibit.

(Bales Exhibit 30 was marked for identification.)

MR. MORIARTY: Do you have a copy for me?

MS. THOMPSON: I do.

THE WITNESS: Okay.

BY MS. THOMPSON:

Q. And this is randomized, controlled trial results, correct? First sentence under "Materials and Methods."

A. Correct.

Q. And the conclusion is just "Trocar Guided..."

And that's Prolift, correct? Prolift is trocar guided, correct?

A. Prolift is trocar guided.

Q. "...transvaginal mesh of anterior

vaginal wall prolapse results in a lowering of MUCPs and increases the risk for de novo stress urinary incontinence compared to colporrhaphy."

Did I read that correctly?

A. You did.

Q. And that would be Level 1 evidence of an increased incidence of stress urinary incontinence de novo after trocar-based mesh, correct?

A. It would be, although a very small experience, 20-plus patients in either group.

MS. THOMPSON: And let's mark this as the next one, whatever it is.

(Bales Exhibit 31 was marked for identification.)

MR. MORIARTY: Is this the last one?

MS. THOMPSON: It is.

BY MS. THOMPSON:

Q. Are you familiar with the paper by --

MR. MORIARTY: Please stop. I need to look at it because you don't have a copy for me.

MS. THOMPSON: And I'm just reading from this. "A significant correlation was found between mesh retraction and the severity

of vaginal pain. Mesh retraction did not differ between patients with de novo SUI symptoms and those without this complication, and this was done with Prolift."

MR. MORIARTY: Objection. Is that a question?

BY MS. THOMPSON:

Q. Did I read it correctly? And this study was using Prolift, correct? You can look in the abstract under "Methods."

A. Prolift, Prolift anterior mesh.

Q. And I'm going to read a statement.

"A significant correlation was found between mesh retraction and the severity of vaginal pain." So at least in this paper a correlation was found between mesh retraction and vaginal pain, correct?

MR. MORIARTY: Objection, form. Go ahead.

A. Evidently, yes.

Q. And this wasn't included in your expert report, was it?

A. No.

MS. THOMPSON: No other questions.

(WHEREUPON, discussion was had off the record.)

BY MS. THOMPSON:

Q. Matt, Dr. Bales, I would like to ask you which products you intend to offer opinions on in the sling cases because that will help us keep our time down tomorrow if we can narrow that down.

A. Sure.

Q. I think counsel told me you were planning on testifying regarding TVT retropubic slings and that would include Exact and mechanical cut and laser cut, correct?

A. Okay.

Q. And then the TVT-O?

A. Correct. Also, I could be asked about Secur.

Q. Okay. So you intend to give opinions about TVT Secur?

A. Well, I'm going to answer your questions.

Q. How about Abbrevo?

A. Never used Abbrevo.

Q. So you would not be offering opinions on Abbrevo?

MR. MORIARTY: Well, you said all of the retropubics. TVT retropubic or classic, correct?

THE WITNESS: Yeah. I mean the Abbrevo --

MR. MORIARTY: TVT-O, TVT-S and any others?

THE WITNESS: No. The Abbrevo and the Exact, as you know, are essentially TVTs with just a shortening of the --

BY MS. THOMPSON:

Q. I agree. I just wanted to make sure I had the products so I know what.

So TVT, because I think Mr. Moriarty told me earlier you were probably not testifying about TVT Secur. So, TVT retropubic, all varieties, TVT-O but not Abbrevo and TVT Secur?

A. Yes, fine.

MS. THOMPSON: I got it.

THE WITNESS: But again you call the shots. You ask the questions.

MR. MORIARTY: Let's go off the record. We don't need to do this on the record.

MS. THOMPSON: No, we don't.

(At 12:36 p.m. the deposition was concluded.)

CERTIFICATE OF CERTIFIED SHORTHAND REPORTER

I, PAULINE M. VARGO, a Certified Shorthand Reporter of the State of Illinois, C.S.R. No. 84-1573, do hereby certify:

That previous to the commencement of the examination of the witness, the witness was duly sworn to testify the whole truth concerning the matters herein;

That the foregoing deposition transcript was reported stenographically by me and thereafter reduced to typewriting under my personal direction;

That the reading and signing of said deposition was reserved by counsel for the respective parties and the witness;

That the foregoing constitutes a true record of the testimony given by said witness before this reporter;

That I am not a relative, employee, attorney or counsel, nor a relative or employee of such attorney or counsel for any of the parties hereto, nor interested directly or indirectly in the outcome of this action.

CERTIFIED TO THIS 6th DAY OF APRIL, A.D., 2016.

_____

Pauline M. Vargo, RPR, CRR
Illinois Certified Shorthand
Reporter No. 84-1573

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

GREGORY BALES, M.D. DATE